

EPA Registration No.  
352-901  
Vol. 1

# MATERIAL TO BE ADDED TO JACKET

REG #: 11654-20

Description: Refined Oil of Nepeta Catarin

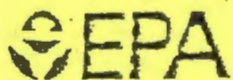
if applicable, check all that are attached:		Send to CSC
<input type="checkbox"/>	new stamped accepted label	
<input type="checkbox"/>	new CSF	
<input type="checkbox"/>	notification	
<input checked="" type="checkbox"/>	other: <u>UNACCEPTABLE Storage Stability</u> <u>Common Characteristic Study</u>	

## Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding the material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

Reviewer: Menyon Adams Date: SEP 01 2010

Phone: (703) 347-8496 Division: BPPD



ADMINISTRATIVE NO(S):: 71654-EN

*Nepeta cataria*

PM: 91

CHEMICAL NO.: \_\_\_\_\_

The jacket for this action can be  
requested through the JACKETS system.

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 01 2010

Thomas C. McEntee  
DuPont Chemical Solutions Enterprise  
P.O. Box 80402  
Wilmington, DE 1988-0402

Subject: Refined Oil of Nepeta Cataria  
EPA Registration No. 71654-20  
Storage Stability and Corrosion Characteristics  
Decision # 434656  
Application Dated: May 21, 2010

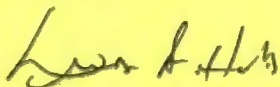
Dear Mr. McEntee:

The Storage Stability and Corrosion Characteristics Guideline study (OPPTS 830.6317 and OPPTS 830.6320) referred to above submitted in response to the terms and conditions of registration as issued December 04, 2008, is **unacceptable but upgradeable**. The following deficiencies need to be addressed:

1. You must clearly demonstrate the stability of the two active ingredients listed on your Confidential Statement of Formula (CSF) by showing whether or not the nominal concentration of these two ingredients are within the certified limits listed on the CSF after 12 months of storage.
2. You must explain the percentage values that are below the lower certified limits for the active ingredients.
3. You must justify why sampling was not performed from each container type at each time interval.

If you have any questions contact Ms. Menyon Adams at 703-347-8496 or by email at:  
[adams.menyon@epa.gov](mailto:adams.menyon@epa.gov).

Sincerely,



Linda A. Hollis, Chief  
Biochemical Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)

## CONCURRENCES

SYMBOL	▶ 7511P						
USERNAME	▶ Adams						
DATE	▶ 09/01/10						



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

MEMORANDUM

DATE: August 25, 2010

SUBJECT: Science Review of Storage Stability and Corrosion Characteristics Studies for Several Products Containing Oil of *Nepeta Cataria* as their Active Ingredient: Refined Oil of *Nepeta cataria* Technical; Refined Oil of *Nepeta cataria* 7% Lotion; Refined Oil of *Nepeta cataria* 15% Lotion; Refined Oil of *Nepeta cataria* 7% Liquid; Refined Oil of *Nepeta cataria* 15% Liquid

EPA File Symbol Numbers: 71654-20; 71654-21; 71654-23; 71654-24; 71654-25  
Decision Numbers: 434656; 434657; 434659; 434660; 434661  
DP Barcode: 378691; 378694; 378693; 378696; 378695  
PC Code: 004801  
CAS Number: 8023-84-5  
MRID Number: 48106201

FROM: Gina M. Casciano, M.S., Biologist /s/ 8/25/2010  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511P)

THROUGH: Russell S. Jones, Ph.D., Senior Biologist /s/ 8/25/2010  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511P)

TO: Menyon Adams, Regulatory Action Leader  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

E. I. du Pont de Nemours and Company requests the review of a recently completed Storage Stability and Corrosion Characteristics study that includes five products containing *Nepeta cataria* oils as their active ingredient (MRID 48106201). Each product was granted a Conditional Section 3(c) Registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) between December 4, 2008, and March 26, 2009.

## RECOMMENDATIONS AND CONCLUSIONS

1. Storage stability data presented appear to indicate that the test substance was stable for 1 year with minimum change in active ingredient concentration and no change in appearance. However, the registrant did not clearly demonstrate that the two active ingredients present in their technical grade active ingredient (TGAI) are stable within the certified limits listed on their Confidential Statement of Formula (CSF). The storage stability analysis is **UNACCEPTABLE**, but upgradable. The registrant must:
  - a. Demonstrate the stability of each of the two ingredients that are listed as active ingredients on the Confidential Statement of Formula (CSF). Specifically, the registrant must show whether or not the nominal concentrations of these two ingredients remain above the lowest respective certified limit after 12 months of storage.
  - b. Explain those values lying outside the active ingredient certified limits for each product.
  - c. Justify why sampling for each container type was not performed at each time interval.
2. The Corrosion Characteristics analysis indicates that the test substance is not corrosive to packaging materials. The corrosion characteristics data are **ACCEPTABLE**; no additional data are required.

## STUDY SUMMARIES

### Storage Stability

The registrant has submitted MRID 48106201 to fulfill the Storage Stability data requirement for the manufacturing-use product (MP) Refined Oil of *Nepeta cataria* (EPA Reg No. 71654-20), and end-use products (EPs) Refined Oil of *Nepeta cataria* 7% Lotion (EPA Reg No. 71654-21), Refined Oil of *Nepeta cataria* 15% Lotion (EPA Reg No. 71654-23), Refined Oil of *Nepeta cataria* 7% Liquid (EPA Reg No. 71654-24), and Refined Oil of *Nepeta cataria* 15% Liquid (EPA Reg No. 71654-25). The study was conducted in accordance with OPPTS Guideline 830.6317 with the following deviations:

- Samples of each product were contained in glass and high density polyethylene (HDPE). Samples of the TGAI/MP were also contained in aluminum (Al). Not all container types were sampled at each time point during the study (0 months, 3 months, 6 months, etc).
- No sample reading were taken at 9 or 12 months. In lieu of a 12-month reading, the samples were read at T = 15 months.

All samples were stored at 25°C and 50% relative humidity for the duration of the study (June, 2001-October, 2008). For each analysis, three portions of the sample to be analyzed were weighted, mixed with a solution of the internal standard 1,2-dibromobenzene and analyzed via

gas chromatograph. (Standards used for calibration/comparison included nepetalactones, dihydronepetalactones, nepetalic acids, pulegic acids, and beta-caryophyllene.) Each of the triplicate samples was analyzed twice in a back to back fashion, thus giving six readings per sampling event. The six values are averaged and these results are displayed in Tables 1-5, below. Because the chromatography can be different for a sample when analyzed as prepared compared to the chromatography of the sample when diluted (sometimes the more concentrated peak will "tail" extensively and can cause the peak not to be within the desired window), all samples were analyzed as prepared, and also analyzed after dilution. The registrant states in their report (MRID 48106201) that the data for the "neat" or "as prepared" samples are reported for reference only, and should not be used in analysis due to the tailing of such peaks and the potentially erroneous GC readings they produce. Therefore, only the results from the diluted preparations are analyzed here.

BPPD has calculated the percent change in active ingredient for each sample. Samples were compared to T = 0 values, unless an analysis was not done at T = 0. Then, the percent change was calculated from the earliest recorded value. **The registrant must justify why sampling did not take place from each container type at each time interval.**

Table 1: Results for Refined Oil of *Nepeta cataria* Technical (EPA Reg No. 71654-20)<sup>†</sup>

	Glass		HDPE		Aluminum	
	% AI	% change	% AI	% change	% AI	% change
T = 0	96.28	n/a	n/d	n/a	n/d	n/a
T = 3 mo	n/d	n/a	85.07	n/a	83.93	n/a
T = 6 mo	92.63	-3.79	93.32	9.70	92.46	10.16
T = 15 mo	91.14	-5.34	93.95	10.44	93.13	10.96

Table 2: Results for Refined Oil of *Nepeta cataria* 7% Lotion (EPA Reg No. 71654-21)<sup>†</sup>

	Glass		HDPE	
	% AI	% change	% AI	% change
T = 0	6.38	n/a	n/d	n/a
T = 3 mo	n/d	n/a	5.89	n/a
T = 6 mo	n/d	n/a	6.81	15.6
T = 15 mo	6.13	-3.92	6.08	3.23

Table 3: Results for Refined Oil of *Nepeta cataria* 15% Lotion (EPA Reg No. 71654-23)<sup>†</sup>

	Glass		HDPE	
	% AI	% change	% AI	% change
T = 0	14.86	n/a	n/d	n/a
T = 3 mo	n/d	n/a	13.17	n/a
T = 6 mo	n/d	n/a	15.48	17.54
T = 15 mo	14.07	-5.32	14.41	9.42

Table 4: Results for Refined Oil of *Nepeta cataria* 7% Liquid (EPA Reg No. 71654-24)<sup>†</sup>

	Glass		HDPE	
	% AI	% change	% AI	% change
T = 0	6.32	n/a	n/d	n/a
T = 3 mo	n/d	n/a	6.19	n/a
T = 6 mo	n/d	n/a	6.87	10.98
T = 15 mo	6.59	4.27	6.5	5.01

Table 5: Results for Refined Oil of *Nepeta cataria* 15% Liquid (EPA Reg No. 71654-25)<sup>†</sup>

	Glass		HDPE	
	% AI	% change	% AI	% change
T = 0	14.00	n/a	n/d	n/a
T = 3 mo	n/d	n/a	13.76	n/a
T = 6 mo	n/d	n/a	15.46	12.36
T = 15 mo	14.20	1.41	14.59	6.03

<sup>†</sup> MRID 48106201, pp 14-15.

The results for the manufacturing-use product (MP) are listed in Table 1. This product, Refined Oil of *Nepeta cataria* (EPA Reg No. 71654-20) has an active ingredient (a.i.) concentration of 100% listed on its label and two components listed as active ingredients on its CSF. **The data presented do not clearly demonstrate that the two active ingredients present in their technical grade active ingredient (TGAI) are stable within the certified limits listed on their CSF. This must be addressed.**

The end-use products (EPs) analyzed in this study were stored and sampled from glass and HDPE containers only. The results for Refined Oil of *Nepeta cataria* 7% Lotion (EPA Reg No. 71654-21) are listed in Table 2. The a.i. concentration listed on the Confidential Statement of Formula (CSF) for this product is 7.0%, with upper and lower certified limits of 7.35% and 6.65%, respectively. Measured concentrations in this study range from 5.89 to 6.81 percent a.i. Specifically, ending values (T = 15 months) are 6.13% for the glass container and 6.08% for the HDPE container. These values are below the lower certified limit for the a.i. **The registrant must explain these a.i. percentage values.**

The results for Refined Oil of *Nepeta cataria* 15% Lotion (EPA Reg No. 71654-23) are listed in Table 3. The a.i. concentration listed on the CSF for this product is 15.0%, with upper and lower certified limits of 15.75% and 14.25%, respectively. The ending concentration for the HDPE container was within these limits at 14.41%. The ending a.i. concentration for the glass container was 14.07, which is below the lower certified limit. **The registrant must explain this value.**

The results for Refined Oil of *Nepeta cataria* 7% Liquid (EPA Reg No. 71654-24) and Refined Oil of *Nepeta cataria* 15% Liquid (EPA Reg No. 71654-25) are listed in Tables 4 and 5, respectively. Both products show a net increase in a.i. concentration over the course of the study.

*Nepeta cataria* oils  
PC Code: 004801

DP Nos: 378691; 378694; 378693; 378696; 378695  
EPA File Symbol Nos.: 71654-20, -21, -23, -24, and -25

However, the starting concentrations of a.i. for both products was below the lower certified limit values listed on the CSF. **The registrant must explain these values.**

**CLASSIFICATION: UNACCEPTABLE, but upgradable.** The registrant demonstrate that the two active ingredients present in their TGAI are stable within the certified limits listed on their Confidential Statement of Formula CSF. The registrant must justify why sampling for each container type was not performed at each time interval. The registrant must also explain values lying outside the active ingredient certified limits.

### **Corrosion Characteristics**

Observations of the samples and packaging used in the above study of Storage Stability lead the study authors to conclude that the test substance is not corrosive to packaging materials. Details of these observations were not included.

**CLASSIFICATION: ACCEPTABLE**, no additional data are required.

Data Evaluation Records (DERs) were not written for this review. For additional information on these Storage Stability and Corrosion Characteristics studies, please refer to MRID 48106201.

cc: G. Casciano, M. Adams, R. S. Jones, BPPD Science Review File, IHAD/ARS  
G. Casciano, Biologist, FT, PY-S: 8/25/2010

# DATA PACKAGE BEAN SHEET

Date: 07-Jun-2010

Page 1 of 2

Decision #: 434656

DP #: (378691)

NON PRIA

Parent DP #:

Submission #: 875462

## \*\*\* Registration Information \*\*\*

Registration: 71654-20 - REFINED OIL OF NEPETA CATARIA

Company: 71654 - E.I. DUPONT DE NEMOURS AND COMPANY

Risk Manager: RM 91 - Linda Hollis - (703) 308-8733 Room# PY1 S-8761

Risk Manager Reviewer: Menyon Adams MADAMS07

Sent Date: 27-May-2010

Calculated Due Date: 14-Sep-2010

Edited Due Date: \_\_\_\_\_

Type of Registration: Product Registration - Section 3

Action Desc: (575) CONDITIONAL REGISTRATION FOLLOW-UP; DATA REQUIRED; REQUIRES SCIENCE

Ingredients: 004801, Nepeta cataria oils(100%)

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 07-Jun-2010

Due Back: \_\_\_\_\_

DP Ingredient: 004801, Nepeta cataria oils

DP Title: \_\_\_\_\_

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: \_\_\_\_\_

### Assigned To

### Date In

### Date Out

Organization: BPPD / BPB

07-Jun-2010

Last Possible Science Due Date: 06-Jul-2010

Team Name: RM 91

07-Jun-2010

Science Due Date: \_\_\_\_\_

Reviewer Name: Jones, Russell Ginz

07-Jun-2010

Sub Data Package Due Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

## \*\*\* Studies Sent for Review \*\*\*

Printed on Page 2

## \*\*\* Additional Data Package for this Decision \*\*\*

No Additional Data Packages

## \*\*\* Data Package Instructions \*\*\*

Attention Russ,  
Please review the storage and stability submission.  
Thanks

Due DATE August 16, 2010

48106201	Davis, E. (2010) One Year Storage Stability Analysis and Container Corrosion Characteristics of Refined Oil of Nepeta cataria and Refined Oil of Nepeta cataria Formulations. Project Number: CCAS/200702/S04, APEX/838/04. Unpublished study prepared by E.I. du Pont de Nemours and Company. 42 p.	830.6320/Corrosion characteristics
48106200	E.I. du Pont de Nemours and Company (2010) Submission of Product Chemistry Data in Support of the Registrations of Refined Oil of Nepeta cataria Technical, Refined Oil of Nepeta cataria 15% Lotion, Refined Oil of Nepeta cataria 7% Lotion, Refined Oil of Nepeta cataria 15% Liquid and Refined Oil of Nepeta cataria 7% Liquid. Transmittal of 1 Study.	
48106201	Davis, E. (2010) One Year Storage Stability Analysis and Container Corrosion Characteristics of Refined Oil of Nepeta cataria and Refined Oil of Nepeta cataria Formulations. Project Number: CCAS/200702/S04, APEX/838/04. Unpublished study prepared by E.I. du Pont de Nemours and Company. 42 p.	830.6317/Storage stability



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

June 3, 2010

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

E.I. DUPONT DE NEMOURS AND COMPANY  
DUPONT CHEMICAL SOLUTIONS ENTERPRISE  
PO Box 80402  
WILMINGTON, DE 19880-0402

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 27-MAY-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3											
S: 875462		Resubmission: <input type="radio"/> Yes <input checked="" type="radio"/> No		<div>Print Letter</div> <div>Enter More Information</div> <div>Tracking</div>							
Regulatory Type: Product Registration - Section 3		Fee For Service: <input type="radio"/> Yes <input checked="" type="radio"/> No									
Application Type: Miscellaneous Receipt		Billable: <input checked="" type="radio"/> Yes <input type="radio"/> No									
Company: 71854 E.J. DUPONT DE NEMOURS AND COMPANY		V									
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91											
Product #: 71854-20		Product Name: REFINED OIL OF NEPETA CATARIA									
Override#:											
Me Too Section3:		Me Too Product Name:									
Application Date: 21-May-2010		OPP Rec'd Date: 27-May-2010		<table border="1"> <thead> <tr> <th>Receipt Content</th> <th>Des</th> </tr> </thead> <tbody> <tr> <td>Study</td> <td></td> </tr> <tr> <td colspan="2"> <div>&lt; 001 &gt;</div> </td> </tr> </tbody> </table> <div>View/Edit</div>		Receipt Content	Des	Study		<div>&lt; 001 &gt;</div>	
Receipt Content	Des										
Study											
<div>&lt; 001 &gt;</div>											
Front End Date: 27-May-2010		Risk Manager Send Date: 27-May-2010									
FFS Due Date:		Negotiated Due Date:									
OPP Target Date:											
Fast Track: <input type="checkbox"/>		New Ingredient: <input type="checkbox"/>									
Receipt Description:											
1 yr. storage stability and corrosion characteristics		New Ingredient Request Date:									
		New Ingredient Received Date:									
Form A: <input type="checkbox"/> Signature Date:		Form B: <input type="checkbox"/> Signature Date:									



DuPont Chemicals and Fluoroproducts

May 21, 2010

Ms. Linda Hollis  
Biopesticides and Pollution Prevention Division (BPPD)  
US Environmental Protection Agency  
Office of Pesticide Programs (7504P)  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

Subject: Refined Oil of *Nepeta cataria* technical; EPA Reg. No. 71654-20  
Refined Oil of *Nepeta cataria* 15% Lotion; EPA Reg. No. 71654-23  
Refined Oil of *Nepeta cataria* 7% Lotion; EPA Reg. No. 71654-21  
Refined Oil of *Nepeta cataria* 15% Liquid; EPA Reg. No. 71654-25  
Refined Oil of *Nepeta cataria* 7% Liquid; EPA Reg. No. 71654-24

Reference: OPPTS 830.6317 (Storage Stability)

Dear Ms. Hollis,

Please refer to the attached study, which was listed as a condition of issuance of the subject registrations.

Should there be any questions, please feel free to call or e-mail.. Thank you for your assistance with our applications.

Sincerely,

A handwritten signature in dark ink, appearing to read "Thomas C. McEntee".

Thomas C. McEntee  
Product Registration Manager  
[Thomas.C.McEntee@usa.dupont.com](mailto:Thomas.C.McEntee@usa.dupont.com)  
(978) 312-1160  
(302) 695-6856

**STUDY TITLE**

One Year Storage Stability Analysis and Container Corrosion  
Characteristics of Refined Oil of *Nepeta cataria* and Refined Oil of *Nepeta*  
*cataria* Formulations

**Test Guidelines**

U.S. EPA Pesticide Assessment Guidelines  
OPPTS Series 830.6317 and 830.6320

VERIFIED COPY of  
ORIGINAL.

**Author**

Edward R. Davis

ORIGINAL RETAINED  
IN CCAS ARCHIVES  
Etp STN BLDG 228 Room 209  
E.R.D.

**Date Study Completed**

21 May 2010

**Performing Laboratory**

E.I. du Pont de Nemours and Company  
Corporate Center for Analytical Science  
Experimental Station  
Wilmington, Delaware 19880-0228

**Project Identification**

CCAS Study Number: CCAS-200702-S04  
CS&E Study Number: Apex 838-04

**Study Sponsor**

DuPont Chemical Solutions Enterprise  
P.O. Box 80402  
Wilmington, DE 19880-0402







U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Biopesticides and Pollution Prevention Division (7511C)  
1200 Pennsylvania Avenue NW  
Washington, DC 20460

EPA Reg.  
Number:

71654-20

Date of Issuance:

DEC 04 2008

NOTICE OF PESTICIDE:

☒ Registration ☐ Re-registration  
(under FIFRA, as amended)

Term of  
Issuance:

Unconditional

Name of Pesticide Product:

Refined Oil of *Nepeta cataria*  
Insect Repellent Technical  
and Manufacturing  
Concentrate

Name and Address of Registrant (include ZIP Code):

DuPont Chemical Solutions Enterprise  
P.O. Box 80402  
Wilmington, DE 1988-0402

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA Sec. 3(c) (5) provided you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Submit within 12 months data package for Guideline Study: OPPTS 830.6317 (Storage Stability).
3. Make the following label change before you release the product for shipment: Revise the EPA Registration Number to read, "EPA Reg. No. 71654-20.
4. Submit three (3) copies of the revised final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

CONCURRENCES

Date:

SYMBOL

SURNAME

DATE

Michael McDavit, Associate Director  
Biopesticides and Pollution  
Prevention Division

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

## Refined Oil of *Nepeta cataria*

Insect Repellent Technical and Manufacturing Use Concentrate for formulation into EPA-registered end-use products designed for application to human skin and clothing for the purpose of repelling insects

### ACTIVE INGREDIENT:

Refined Oil of *Nepeta cataria*.....100%

EPA Reg. No. 71654-20

EPA Est. No. XXXXX-YY-ZZZ

**KEEP OUT OF REACH OF CHILDREN**

### CAUTION

See [Back Panel][Side Panel][Product Leaflet] for Additional Precautions

Manufactured By:  
E.I. du Pont de Nemours and Company  
PO Box 80402  
Wilmington, DE 19880-0402

Net Contents: \_\_\_\_\_

### PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed. Avoid Contact with Skin, Eyes or Clothing. Causes Eye Irritation. Do not get in eyes, on skin or clothing.

### PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame.

### ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of EPA. Keep out of lakes, ponds or streams.

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**ACCEPTED**

**DEC 04 2008**

Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended, for  
the pesticide registered under  
EPA Reg. No. 71654-20

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirement specific to your State and Tribe, consult the State/Tribal agency responsible for pesticide regulation.

**FOR MANUFACTURING USE ONLY:** Use only for formulation into EPA-registered end-use products designed for application to human skin and clothing for the purpose of repelling insects.

<b>FIRST AID</b>	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
<b>If in Eyes:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.</li> <li>• Call a Poison Control Center or doctor for further treatment advice.</li> </ul>
<b>If on Skin or Clothing:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a Poison Control Center or doctor for further treatment advice.</li> </ul>
<b>If Swallowed:</b>	<ul style="list-style-type: none"> <li>• Call Poison Control Center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor</li> <li>• Do not give anything by mouth to an unconscious person</li> </ul>
<b>If Inhaled</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>• Call Poison Control Center or doctor for further treatment advice.</li> </ul>
<b>Emergency Contact Number: 1-800-3637(US &amp; Canada) or 1-302-774-1139 (all other areas).</b>	
For 24-hour transportation emergency information on this product, call Chemtrec at 1-800-424-9300 (US Canada, Puerto Rico, & Virgin Islands); 1-703 527-3887 (all other areas)	
<b>Note to Physician:</b> Probable mucosal damage may contraindicate the use of gastric lavage.	

## **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**Storage:** Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 130°F (54°C).

**Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Biopesticides and Pollution Prevention Division (7511C)  
1200 Pennsylvania Avenue NW  
Washington, DC 20460

EPA Reg.  
Number:

71654-20

Date of Issuance:

DEC 04 2008

NOTICE OF PESTICIDE:

☒ Registration ☐ Re-registration  
(under FIFRA, as amended)

Term of  
Issuance:

Unconditional

Name of Pesticide Product:

Refined Oil of *Nepeta cataria*  
Insect Repellent Technical  
and Manufacturing  
Concentrate

Name and Address of Registrant (include ZIP Code):

DuPont Chemical Solutions Enterprise  
P.O. Box 80402  
Wilmington, DE 1988-0402

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA Sec. 3(c) (5) provided you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Submit within 12 months data package for Guideline Study: OPPTS 830.6317 (Storage Stability).
3. Make the following label change before you release the product for shipment: Revise the EPA Registration Number to read, "EPA Reg. No. 71654-20.
4. Submit three (3) copies of the revised final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

CONCURRENCES

Date:

SYMBOL

SURNAME

DATE

Michael McDavit, Associate Director  
Biopesticides and Pollution  
Prevention Division

## Refined Oil of *Nepeta cataria*

Insect Repellent Technical and Manufacturing Use Concentrate for formulation into EPA-registered end-use products designed for application to human skin and clothing for the purpose of repelling insects

### ACTIVE INGREDIENT:

Refined Oil of *Nepeta cataria*.....100%

EPA Reg. No. 71654-20

EPA Est. No. XXXXX-YY-ZZZ

**KEEP OUT OF REACH OF CHILDREN**

### CAUTION

See [Back Panel][Side Panel][Product Leaflet] for Additional Precautions

Manufactured By:

E.I. du Pont de Nemours and Company

PO Box 80402

Wilmington, DE 19880-0402

Net Contents: \_\_\_\_\_

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed. Avoid Contact with Skin, Eyes or Clothing. Causes Eye Irritation. Do not get in eyes, on skin or clothing.

#### PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame.

#### ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of EPA. Keep out of lakes, ponds or streams.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.




ACCEPTED

DEC 04 2008

Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended, for  
the pesticide registered under  
EPA Reg. No. 71654-20

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirement specific to your State and Tribe, consult the State/Tribal agency responsible for pesticide regulation.

**FOR MANUFACTURING USE ONLY:** Use only for formulation into EPA-registered end-use products designed for application to human skin and clothing for the purpose of repelling insects.

<b>FIRST AID</b>	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
<b>If in Eyes:</b> <ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.</li> <li>• Call a Poison Control Center or doctor for further treatment advice.</li> </ul>	
<b>If on Skin or Clothing:</b> <ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a Poison Control Center or doctor for further treatment advice.</li> </ul>	
<b>If Swallowed:</b> <ul style="list-style-type: none"> <li>• Call Poison Control Center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor</li> <li>• Do not give anything by mouth to an unconscious person</li> </ul>	
<b>If Inhaled</b> <ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>• Call Poison Control Center or doctor for further treatment advice.</li> </ul>	
<b>Emergency Contact Number: 1-800-3637(US &amp; Canada) or 1-302-774-1139 (all other areas).</b>	
For 24-hour transportation emergency information on this product, call Chemtrec at 1-800-424-9300 (US Canada, Puerto Rico, & Virgin Islands); 1-703 527-3887 (all other areas)	
<b>Note to Physician:</b> Probable mucosal damage may contraindicate the use of gastric lavage.	

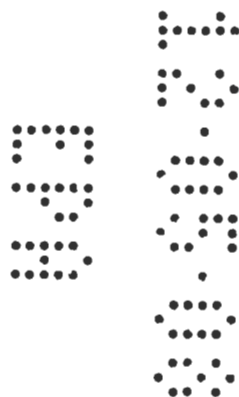
## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**Storage:** Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 130°F (54°C).

**Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

**MEMORANDUM**

**SUBJECT:** Consideration of a unconditional registration of the active ingredient Refined Oil of *Nepeta cataria* (PC Code 004801), EPA Identifying Symbol 71654-EN. The Technical Grade of the Active Ingredient (TGAI) is intended for use in the formulation of a dermal applied insect repellent for direct application to human skin to repel black flies, mosquitoes and other biting insects.

----- **DECISION MEMORANDUM** -----

**FROM:** W. Michael McDavit, Associate Director  
Biopesticides and Pollution Prevention Division

*W. Michael McDavit*  
12/1/08

**TO:** Debra Edwards, Ph. D., Director  
Office of Pesticide Programs

**ISSUE**

Should the Agency grant an unconditional registration under FIFRA § 3(c)(5) for the new biochemical active ingredient, Refined Oil of *Nepeta cataria* (PC Code 004801), EPA Identifying Symbol 71654-EN) to be used in the formulation of end-use products intended as an insect repellent for direct application to human skin to repel black flies, mosquitoes and other biting insects?

**APPLICANT INFORMATION**

On October 12, 2006 Dupont Chemical Solutions Enterprise submitted an application for the registration of a new biochemical pesticide Technical (TGAI), containing the active Refined Oil of *Nepeta cataria*. A notice of receipt of this application was published in the Federal Register February 27, 2008 (73 FR 10434-35) with a 30-day comment period. No comments were received following this publication.

## **BACKGROUND AND CONCLUSIONS**

The Biopesticides and Pollution Prevention Division (BPPD) reviewed available and submitted data and information regarding the proposed use of Refined Oil of *Nepeta cataria*. Evaluations of the submitted information and conclusions are summarized and discussed in the attached Biopesticide Registration Action Document (BRAD). The technical grade active ingredient (TGAI) is comprised of dihydronepetalactone and pulegic acid. The plant is commonly known as catnip. Historical use of the active ingredient has been as an herbal medicine to treat fever, head and tooth aches, colds, colic and spasms in humans. It has also been used to induce sleep in some individuals, but as a stimulant in others. Other historical uses include the use of this active as a meat rub with catnip leaves, additive to salads or used to make tea.

BPPD has considered Refined Oil of *Nepeta cataria* in light of relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and determined there will be no unreasonable adverse effects from the use of this product. BPPD has considered available information on Refined Oil of *Nepeta cataria* including its medicinal uses and as an emetic (at high doses) in cats and humans, and the lack of reported adverse effects. BPPD believes that end use products which are formulated using Refined Oil of *Nepeta cataria* and used as an insect repellent for direct application to human skin can be used without causing unreasonable adverse effects to humans or the environment.

The information submitted by the applicant and reviewed by BPPD support the application to register the Technical Grade of the Active Ingredient containing the new biochemical Refined Oil of *Nepeta cataria* when applied / used as directed on the label.

## **OFFICE DIRECTOR CONCURRENCE**

Based on the discussion above and the summarized data evaluations in the attached BRAD, BPPD recommends that the TGAI Refined Oil of *Nepeta cataria* containing the new biochemical active ingredient at 100.00% (PC Code 04801) is unconditionally registered under 3(c)(5) of FIFRA for use to control slugs and snails.

Concurrence: \_\_\_\_\_



Non Concurrence: \_\_\_\_\_

Date: \_\_\_\_\_

12/3/08

**BIOPESTICIDES REGISTRATION ACTION DOCUMENT**

**Refined Oil of *Nepeta casaria*  
[Hydrogenated Catmint Oil (HCO)]**

**U.S. Environmental Protection Agency  
Office of Pesticide Programs  
Biopesticides and Pollution Prevention Division**

(Last updated November 28, 2008)

*This document is for informational purposes only and is representative of the Agency's justification in registering products containing this active ingredient. This is not a legal document. (Need OGC language)*

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**BIOPESTICIDES REGISTRATION ACTION DOCUMENT TEAM**

**Office of Pesticide Programs:**

**Biopesticides and Pollution Prevention Division**

**Biochemical Pesticides Branch (BPB)**

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<i>Raderrio Wilkins</i>	Regulatory Action Leader
<i>Kent Carlson, Ph.D.</i>	Biologist, Product Chemistry
<i>Clara Fuentes, Ph.D.</i>	Biologist, Product Performance
<i>Roger Gardner</i>	Senior Toxicologist, Acute Toxicology

## I. EXECUTIVE SUMMARY:

The active ingredient is a refined, multi-component extract of Oil *Nepeta cataria* which is a member of the mint family of plants (*Labiatae*). The technical grade active ingredient (TGAI) is identified as Refined Oil of *Nepeta cataria* and is also referred to as Hydrogenated Catmint Oil (HCO). The technical grade active ingredient is intended for use in the manufacture of a dermal applied insect repellent for direct application to human skin to repel black flies, mosquitoes and other biting insects.

The Biopesticides and Pollution Prevention Division (BPPD) has determined that the data/information submitted for Tier I Acute Toxicity and Product Chemistry adequately satisfy current guideline requirements (refer to 40 CFR Subpart U § 158.2000). Non-target toxicology data requirement were satisfied by the submission of data waivers for non-target organism granted by BPPD based on the low quantity of Refined Oil of *Nepeta cataria*, limited breadth of application and low hazards to non-target species presented in the scientific literature and rationale for the proposed use of Refined Oil of *Nepeta cataria* as an insect repellent. This will preclude significant adverse exposure and risk to non-target organisms. Based on the information discussed above, the Agency has determined that Technical Grade of Refined Oil of *Nepeta cataria* as an active ingredient will have **No Adverse Effects (NAE)** on threatened and/or endangered species.

Based on the Acute Toxicity and Product Chemistry data available to the Agency, the technical grade active ingredient is classified into Toxicity Category III for oral toxicity and primary eye irritation and Toxicity Category IV for dermal, inhalation and skin irritation. The Agency has determined that no unreasonable adverse effects to the U.S. population will result from the use of the active ingredient when label instructions are followed. There are no reports of adverse effects following regular human exposure and consumption of Refined Oil of *Nepeta cataria*. Moreover, the pesticidal usage of this biochemical will not have any harmful environmental effects.

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed data /information in support of the requirements for granting registration under Section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It was determined that the data/information submitted adequately satisfy current guideline requirements (refer to 40 CFR Subpart U § 158.2000).

## II. ACTIVE INGREDIENT OVERVIEW

**Common Name:** Hydrogenated catmint oil (HCO)

**Chemical Names:** Refined Oil of *Nepeta cataria*

**Trade & Other Names:** Refined Oil of *Nepeta cataria*

**CAS Registry Number:** 8023-84-5

**OPP Chemical Code:** 004801

**Type of Pesticide:** Biochemical pesticide (Insect Repellent)

Application rates and methods vary depending on the product. For specific information regarding the product(s) refer to Appendix B.

## III. REGULATORY BACKGROUND

Dupont Chemical Solutions Enterprise submitted an application for the registration of a new biochemical pesticide Technical (TGAI), containing the active ingredient Refined Oil of *Nepeta cataria* on October 12, 2006. A notice of receipt of an application for registration of Refined Oil of *Nepeta cataria* as an active ingredient, was published in the Federal Register on February 27, 2008 (73 FR 10434-35) with a 30-day comment period. No comments were received following this publication.

### A. Classification

On February 27, 2006, the Biochemical Classification Committee determined that Refined Oil of *Nepeta cataria* qualified to be reviewed in BPPD for a reduced data set. The classification is based on the active ingredient being derived from a natural and botanical source, its low toxicity, and its use as a medicinal and nutritional ingredient for humans.

### B. Food Clearances/Tolerances

Currently, this active ingredient is proposed for non food or feed uses.

## IV. RISK ASSESSMENT

### A. Active Ingredient Characterization

The active ingredient is a refined, multi-component extract of *Nepeta cataria* which is a member of the mint family of plants (*Labiatae*). The technical grade active ingredient (TGAI) is identified on proposed product labels as Refined Oil of *Nepeta cataria* and is also referred to as Hydrogenated Catmint Oil (HCO). The plant is commonly known as catnip and is indigenous from eastern Mediterranean to eastern Himalayan regions. The perennial herb can also be grown in North America. General information on the nature of the active ingredient is readily available (e.g., <http://chemistry.about.com/library/weekly/aa103001a.htm>; accessed on October 2, 2007) and is summarized as background information below.

Nepetalactone is the major component of the refined oil, but there are other components such as puleganic acid with known insect repellent activity. Nepetalactone is a terpene comprised of two isoprene units, and it has a chemical structure similar to that of the valepotrates (from the herb valerian) which have mild central nervous system effects in humans (sedative or stimulant depending on the individual).

Historically, Refined Oil of *Nepeta cataria* has been used in herbal medicine to treat fever, head and tooth aches, colds, colic and spasms in humans. In some individuals catnip can be used to induce sleep, but it can also act as a stimulant in others. At high doses it is emetic in cats and humans. Other historical uses included rubbing meat with catnip leaves, adding it to salads or making tea with it. The principal insect repellent components in Refined Oil of *Nepeta cataria* are dihydronepetalactone (69.99% w/w) and puleganic acid (6.77% w/w).

The description of the production process on the technical (TGAI), as well as the formation of impurities, were examined by the Agency and found to be acceptable in meeting current guideline standards. The analytical method used to determine the content of the active ingredient is also acceptable. Physical and chemical properties were submitted for the technical grade active ingredient and are adequate. Refer to Table 1 in Appendix A for a summary of product chemistry data requirements. Refer to Table 2 in Appendix A for the summary of physical and chemical characteristics for technical grade Refined Oil of *Nepeta cataria*.

All product chemistry data requirements for registration of Refined Oil of *Nepeta cataria* as the TGAI have been **satisfied**.

## **B. Human Health Assessment**

### **1. Toxicology**

For acute toxicity data requirements, toxicity categories are assigned based on the hazard(s) identified from studies and/or information on file with the Agency. The active ingredient is classified into Toxicity Category I, II, III or IV where Toxicity Category I indicates the highest toxicity and Toxicity Category IV indicates the lowest toxicity. For more information, refer <http://www.epa.gov/pesticides/pestlabels/>.

Technical grade Refined Oil of *Nepeta cataria* is classified into Toxicity Category III for oral toxicity and primary eye irritation and Toxicity Category IV for dermal, inhalation and skin irritation. It is not a skin sensitizer.

The registrant submitted a discussion (MRID 47362604) that addressed the questions EPA had regarding a positive mouse lymphoma assay. The discussion provided an acceptable rationale for the TGAI being non-genotoxic and explores the concept of false test positives and weight of the evidence.

Adequate mammalian toxicology data/information is available to support registration of the technical grade active ingredient, Refined Oil of *Nepeta cataria*. All toxicology data requirements for the technical grade active ingredient (TGAI) have been **satisfied**.

### **a. Acute Toxicity**

Acute toxicity studies submitted in support of the technical grade active ingredient, Refined Oil of *Nepeta cataria* are summarized in Table 3 in Appendix A. Refined Oil of *Nepeta cataria* is classified in Toxicity Category III for acute oral toxicity and primary eye irritation and Toxicity Category IV for acute dermal, acute inhalation and skin irritation. It is not a dermal sensitizer. Based on the review and analysis of the information, guideline studies, and submitted literature discussed in detail in this section of the BRAD, no additional toxicity data are required to support the non food use of this of this active ingredient.

### **b. Subchronic Toxicity**

In an acceptable oral toxicity study (MRID 46977407), hydrogenated catmint oil (HCO) was administered by gavages daily to groups of ten rats/sex at doses of 0, 40, 200, and 1000 mg/kg body weight for 93 days. Hematological, clinical chemistry, urinalysis, ophthalmoscopic, neurological, and microscopic tissue and organ effects were determined only in the subchronic studies. All rats in the study survived until scheduled sacrifice. The only persistent clinical observation reported was perineal staining throughout the study on three female high-dose rats. No neurological or ophthalmoscopic effects were noted. The subchronic oral toxicity study in rats demonstrated a no-observed-effect level (NOEL) of 200 mg/kg/day and a lowest-observable-effect level (LOEL) of 1000 mg/kg/day based on the increased incidence of minimal to mild degeneration/regeneration of the olfactory epithelium lining the nasal turbanates of treated male and female rats. No systemic toxicity was observed in the subchronic dermal toxicity study at dose levels up to 1000 mg/kg/day.

### **c. Developmental Toxicity and Mutagenicity**

There were no adverse effects observed in a 28-day oral immunotoxicity study or in a developmental toxicity study at oral doses up to 1000 mg/kg/day. No genetic toxicity was observed in bacteria (point mutation assay), an in vitro cytogenetics assay, or in a mouse micronucleus assay. However, a point mutation assay in mouse lymphoma cells reported an increased frequency of point mutations at doses approaching cytotoxic levels without metabolic activation. The registrant submitted a discussion (MRID 47362604) that addressed the questions EPA had regarding a positive mouse lymphoma assay. The discussion provided an acceptable rationale for the TGA being non-genotoxic and explores the concept of false test positives and weight of the evidence.

### **e. Effects on the Endocrine System**

EPA is required under the Federal Food, Drug, and Cosmetics Act (FFDCA), as amended by the Food Quality Protection Act (FQPA), to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For

pesticide chemicals, the Agency will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency is not requiring information on the endocrine effects of Refined Oil of *Nepeta cataria* at this time. The Agency has considered, among other relevant factors, available information concerning whether the active ingredient may have an effect on humans similar to an effect produced by naturally-occurring estrogen or other endocrine effects. There is no known metabolite that acts as an endocrine disrupter produced by this active ingredient. Based on the low potential exposure level associated with the proposed use of the end use products, the Agency expects no incremental adverse effects to the endocrine or immune systems.

## **2. Dose Response Assessment**

No toxicological endpoints were identified; therefore, a dose response assessment was not required.

## **3. Drinking Water Exposure and Risk Characterization**

No significant exposure via drinking water is expected when Refined Oil of *Nepeta cataria* is used according to the product label directions. The technical grade active ingredient is intended for use in the manufacture of a dermal applied insect repellent for direct application to human skin and not to be applied directly to water or to areas where surface water is present, and if used as labeled, is not likely to accumulate in drinking water. In the unlikely event that exposure via drinking water did occur, the health risk would be expected to be minimal, based on the low acute oral and dermal toxicity of Refined Oil of *Nepeta cataria*.

## **4. Occupational, Residential, School and Day Care Exposure and Risk Characterization**

### **a. Occupational Exposure and Risk Characterization**

No occupational estimates are made in this assessment since Refined Oil of *Nepeta cataria* is to be used by individuals as an insect repellent that they apply directly to their own skin. Non-occupational dermal exposure estimates were not determined because the subchronic dermal toxicity study did not demonstrate an endpoint for use in risk characterization, human skin is much less permeable to Refined Oil of *Nepeta cataria* than rat skin (MRID 47015601), and the label indicates that advice from a physician or Poison Control Center should be sought when reactions to exposure from use of the products are suspected. Again, the directions for use on the proposed end use labels indicated that application of the lotions or liquid sprays to children's fingers and hands was to be avoided. Therefore, no exposure estimates were determined for incidental oral exposure.

## **b. Residential, School and Day Care Exposure and Risk Characterization**

Since the technical grade active ingredient is intended for use in the manufacture of a dermal applied insect repellent for direct application to human skin, significant human exposure to Refined Oil of *Nepeta cataria* will be minimal in residential, school and day care areas when the end use product is used according to the label directions. The acute neurotoxicity endpoint is appropriate to an incidental oral exposure for children, but because the effect is reversible and pharmacological in nature (reduced activity) and the label contains instructions to avoid incidental exposure (i.e., licking of fingers and hands), no risk characterization was done for incidental oral scenarios. Should accidental exposure occur, the health risk is expected to be minimal, based on the low acute oral, dermal, and inhalation toxicity of Refined Oil of *Nepeta cataria*.

## **5. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation**

There is reasonable certainty that no harm to the US population will result from aggregate exposure to Refined Oil of *Nepeta cataria*. The Agency arrived at this conclusion based on the low level of toxicity of Refined Oil of *Nepeta cataria* and the current use as a food ingredient by the general public without any reported adverse effects on human health. The risks from aggregate exposure via oral, dermal and inhalation exposure are a compilation of three low-risk exposure scenarios and are negligible. Since there are no threshold effects of concern, the provision requiring an additional margin of safety does not apply. Therefore, the Agency has not used a margin of exposure (safety) approach to assess the safety of Refined Oil of *Nepeta cataria*.

## **6. Cumulative Effects**

Based on the information available to the Agency, there is no indication that toxic effects associated with exposure to Refined Oil of *Nepeta cataria* are of toxicological concern. Because the technical grade active ingredient's low toxicity, cumulative effects with other substances that share a common mechanism of toxicity are not expected.

## **7. Risk Characterization**

The Agency considered human exposure to Refined Oil of *Nepeta cataria* in light of the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result from the use of Refined Oil of *Nepeta cataria* when label instructions are followed.

# **C. ENVIRONMENTAL ASSESSMENT**

## **1. Ecological Hazards**

Ecological effects data requirements for technical grade Refined Oil of *Nepeta cataria* were satisfied by the submission of data waiver requests pertaining to effects on Non-Target organisms. Based on the waiver rationale, the Agency concluded that exposure and risk from the proposed use of the manufacture and integration of the technical grade Refined Oil of *Nepeta cataria* into a formulated product is not expected to occur or pose a threat to non-target

organisms. Since the active ingredient is a technical grade product, non-target requirements can be waived by the submissions of data waivers which will be a condition of the registration.

## 2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data was not triggered because Refined Oil of *Nepeta cataria* results of the acute toxicity studies did not trigger any additional Tier I studies.

## 3. Ecological Exposure and Risk Characterization

Based on the rationales submitted in the data waiver requests, exposure and risk from the proposed use of the manufacture and integration of the technical grade Refined Oil of *Nepeta cataria* into a formulated product is not expected to occur for non-target organisms.

## 4. Endangered Species Assessment

Based on the information discussed above, the Agency has determined that registered use of Refined Oil of *Nepeta cataria* as an active ingredient will have **No Adverse Effects (NAE)** on threatened and/or endangered species. When the product is used according to label use directions, there are no concerns for any non-target organisms.

## V. Risk Management Decision

### A. Determination of Eligibility for Registration

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The four criteria of the Eligibility Determination for Pesticidal Active Ingredients are satisfied by the science assessments supporting products containing Refined Oil of *Nepeta cataria*. Such products are not expected to cause unreasonable adverse effects, and are likely to provide protection as claimed when used according to label instructions. Therefore, Refined Oil of *Nepeta cataria* is eligible for registration for the labeled uses.

### B. Regulatory Decision

The data submitted fulfill the requirements of registration for use of Refined Oil of *Nepeta cataria* for use in the manufacture of a dermal applied insect repellent for direct application to human skin to repel black flies, mosquitoes and other biting insects. Refer to Appendix B for product-specific information.

## 1. Conditional/Unconditional Registration

All data requirements are fulfilled and EPA has determined that unconditional registration of technical grade Refined Oil of *Nepeta cateria* is appropriate.

### **C. Environmental Justice**

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to Refined Oil of *Nepeta cateria*, compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.

## **VI. ACTIONS REQUIRED BY REGISTRANTS**

The Agency evaluated all of the data submitted in connection with the initial registration of technical grade Refined Oil of *Nepeta cateria* and determined that these data are sufficient to satisfy current registration data requirements. No additional data are required to be submitted to the Agency at this time. For new uses and/or changes to existing uses, additional data may be required.

Notwithstanding the information stated in the previous paragraph, it should be clearly understood that certain, specific, data are required to be reported to the Agency as a requirement for maintaining the Federal registration for a pesticide product. A brief summary of these types of data are listed below.

### **A. Reporting of Adverse Effects**

Reports of all incidents of adverse effects to the environment must be submitted to the Agency under the provisions stated in FIFRA, Section 6(a)(2).

### **B. Reporting of Hypersensitivity Incidents**

Additionally, all incidents of hypersensitivity (including both suspected and confirmed incidents) must be reported to the Agency under the provisions of 40 CFR Part 158.2050(d).

## VII. Appendix A. Data Requirements (40 CFR Part 158-Subpart U)

\*NOTE: MRID numbers listed in the following tables are representative of supporting data for the original registration of the product containing this active ingredient. Subsequent to this registration, there may be additional MRIDs that support registration of other products containing this active ingredient.

TABLE 1. Product Chemistry Data Requirements for Refined Oil of <i>Nepeta cataria</i> (40 CFR § 158.2030)		
OPPTS Guideline No.	Study	Results (below are example results)
830.1550 to 830.1670	Product identity; Manufacturing process; Discussion of formation of unintentional ingredients	Submitted data satisfy the requirements for product identity, manufacturing process, and discussion of formation of impurities.
830.1700	Analysis of samples	Submitted data satisfy the requirements for analysis of samples.
830.1750	Certification of limits	Limits listed in the CSF are adequate / acceptable.
830.1800	Analytical method	Acceptable.

TABLE 2. Physical and Chemical Properties of Refined Oil of <i>Nepeta cataria</i> (40 CFR § 158.2030)		
OPPTS Guideline No.	Property	Description of Result
830.6302	Color	Yellow @ 21°C
830.6303	Physical State	Liquid @ 21°C
830.6304	Odor	Minty
830.6313	Stability to Normal and Elevated Temperatures, Metals and Metal Ions	Stable at room and elevated temperatures and in the presence of metals and ions.
830.6314	Oxidation/Reduction: Chemical Incompatibility	Dihydronepetalactone was relatively stable in solution with metals and metal salts after 14 days at 25°C, with slight decreases at 54°C after 14 days.
830.6315	Flammability	>99°C
830.6317	Storage Stability	In short-term testing at 25 and 54°C, dihydronepetalactone content was relatively stable. Guideline study is in progress.
830.6319	Miscibility	Not applicable, product is not to be diluted in petroleum solvents
830.6320	Corrosion Characteristics	Guideline study is in progress
830.7000	pH	3.97 @ 25°C (1% w/w in deionized water)
830.7050	UV/Visible Light Absorption	Not applicable
830.7100	Viscosity	18.09 mm <sup>2</sup> /s (cSt) @ 22°C
830.7200	Melting Point/Range	Not applicable, product is a liquid
830.7220	Boiling Point/Range	266.0 ± 12.0°C
830.7300	Density	1.0334 @ 20.7°C
830.7520	Particle Size, Fiber Length and Diameter Distribution	
830.7550 830.7560 830.7570	Partition Coefficient (n- Octanol/Water)	Not applicable, required only for pure active ingredient
830.7840	Water Solubility	0.254 ± 0.013 g/L @ 30°C
830.7950	Vapor Pressure	591, 707, 907, 1100, 1320, and 1630 Pa @ 20, 25, 30, 35, and 40°C, respectively

**Table 3. Human Toxicology Data Requirements for Refined Oil of Refined Oil of *Nepeta cataria* (40 CFR § 158.2050)**

Study/OPPTS Guideline No.	Results	Toxicity Category/Description
Acute oral toxicity (rat) (870.1100)	LD <sub>50</sub> = 1750 (95% C.L. 455.5-9230) mg/kg (females using the Up-and Down Method)	III / MRID 46977401
Acute dermal toxicity (rat) (870.1200)	LD <sub>50</sub> > 5000 mg/kg for males, females, and for both sexes combined.	IV / MRID 46977402
Acute inhalation toxicity (rat) (870.1300)	LC <sub>50</sub> > 5.5 mg/L (males, females, and both sexes combined; 4 hour nose-only exposure)	IV / MRID 46977406
Primary eye irritation (rabbit) (870.2400)	Corneal opacity persisted for 24 to 48 hours after treatment with clearance by 72 hours. Iritis was noted at 1 and 24 hours after treatment and cleared by the 48 hour observation. Conjunctival irritation was noted on one rabbit one hour throughout 48 hours after treatment with clearance by 72 hours. The maximum average score was 24.0 at 24 hours after test material instillation. Hydrogenated Catmint Oil was mildly irritating.	III / MRID 46977403
Primary dermal irritation (rabbit) (870.2500)	No dermal irritation or clinical signs of toxicity were observed during the study. The primary irritation index was 0.0.	IV / MRID 46977404
Dermal sensitization (mouse) (870.2600)	A local lymph node assay (LLNA) indicated that hydrogenated catmint oil is not a dermal sensitizer.	--- / MRID 46977405
90-Day oral toxicity (rat) (870.3100)	Minimal to mild degeneration / regeneration of the olfactory epithelium lining the nasal turbinates of males and females. NOAEL = 200 mg/kg LOAEL = 1000 mg/kg	MRID 46977407
90-Day dermal toxicity (rat) (870.3250)	No adverse effects were reported. NOAEL = 1000 mg/kg LOAEL > 1000 mg/kg	MRID 46977415
Mutagenicity (Bateria) (870.5100, 5300 and 5375)	Negative Doses tested: 0 to 5000 µg/plate with or without metabolic activation (S9 mix)	MRID 46977410
Developmental toxicity (rat) (870.3700)	No adverse effects were reported. NOAEL = 1000 mg/kg LOAEL > 1000 mg/kg	MRID 46977408

TABLE 4. Non-Target Organism Toxicity Requirements for Refined Oil of <i>Nepeta cataria</i> (40 CFR § 158.2060)		
Study/OPPTS Guideline No.	Results	Toxicity Category/Description
Avian acute oral toxicity <i>Colinus virginianus</i> (850.2100)	Data Waiver Request submitted	
Avian dietary toxicity <i>Colinus virginianus</i> (850.2200)	Data Waiver Request submitted	
Avian dietary toxicity <i>Anas platyrhynchos</i> (850.2200)	Data Waiver Request submitted	
Aquatic invertebrate acute toxicity ( <i>Daphnia magna</i> ) (850.1010)	Data Waiver Request submitted	
Freshwater fish LC <sub>50</sub> ( <i>Oncorhynchus mykiss</i> ) (850.1075)	Data Waiver Request submitted	
Non-target plant studies (850.4000-4800, as applicable)	Data Waiver Request submitted	
Non-target insect testing (880.4350)	Data Waiver Request submitted	

#### VIII. Appendix B.

For product specific information, please refer to <http://www.epa.gov/pesticides/pestlabels>

11/28/88  
Please Review  
per my comment

## Refined Oil of *Nepeta cataria*

Insect Repellent Technical and Manufacturing Use Concentrate

ACTIVE INGREDIENT:

Refined Oil of *Nepeta cataria*.....100.0%

for formulation into end use products to do .....

EPA Reg. No. 71654-

EPA Est. No. XXXXX-YY-ZZZ

**KEEP OUT OF REACH OF CHILDREN**

### CAUTION

See [Back Panel][Side Panel][Product Leaflet] for Additional Precautions

Manufactured By:

E.I. du Pont de Nemours and Company

PO Box 80402

Wilmington, DE 19880-0402

Net Contents: \_\_\_\_\_

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed. Avoid Contact with Skin, Eyes or Clothing. Causes Eye Irritation. Do not get in eyes, on skin or clothing.

#### PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame.

#### ENVIRONMENTAL HAZARDS

Keep out of lakes, ponds or streams.

→ you need a discharge statement for MDA

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

apply this product in a way that will... eat.

Refer to technical data sheet for instructions on the formulation of end-use EPA-registered insect repellent formulations.

Do not

Incomplete (you need full discharge statement)

## FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

### If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

### If on Skin or Clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for further treatment advice.

### If Swallowed:

- Call Poison Control Center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

### If Inhaled

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call Poison Control Center or doctor for further treatment advice.

**Emergency Contact Number: 1-800-3637(US & Canada) or 1-302-774-1139 (all other areas).**

For 24-hour transportation emergency information on this product, call Chemtrec at 1-800-424-9300 (US Canada, Puerto Rico, & Virgin Islands); 1-703 527-3887 (all other areas)

**Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage.

## STORAGE AND DISPOSAL


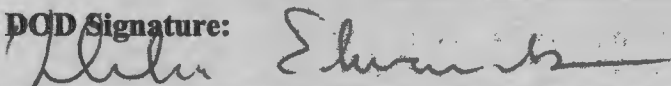
Do not contaminate water, food or feed by storage or disposal.

**Storage:** Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 130°F (54°C).

**Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Disposal:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**Recommendation of Division Directors  
Negotiated Due Dates**

<b>Decision#:</b> 371861	<b>Registration#:</b> 71654-EN (TGAI)	<b>Petition #:</b> N/A
<b>Fee Category:</b> B60 (PRIA 1)		<b>PRIA Decision Time Frame:</b> 12 months
<b>Submitted by:</b> Raderrio Wilkins	<b>Branch:</b> BPB	<b>Date:</b> November 26, 2008
<b>Company:</b> Dupont Chemical Solution		
<b>Original Due Date:</b> Nov. 17, 2007		<b>Proposed New Due Date:</b> December 5, 2008
<b>Previous Negotiated Due Dates:</b> 11/17/07, 5/30/08, and 11/30/08		
<b>Is the "Fix" in-house?</b> YES		<b>If not, date "Fix" expected:</b>
<b>Issue (describe in detail):</b> BPPD needs additional administrative time to review the supplemental information and BRAD.		
<b>Summary of Deficiency Type(s):</b> Not Submitted (N) Deficiencies <del>(S)</del> <b>Product Chemistry:</b> <del>___</del> <b>Acute Tox:</b> <del>___</del> <b>Efficacy:</b> <del>___</del> <b>Labeling:</b> ___ <b>Other (describe):</b> ___		
<b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b> The company's agent (Mr. Thomas McEntee) is extremely slow in responding to Agency letters, emails and telephone messages initiated by the Regulatory Manager and Branch Chief.		
<b>"75 Day" Letter sent?</b> <u>10/16/08 and 11/13/08</u> (Date sent) Yes ___ No and reason for none? ___		
<b>Note:</b> Application was submitted under PRIA 1		
<b>Rationale for Proposed Due Date:</b> The resubmitted information would require BPPD Phase review of Phases III – V, which is equivalent to one week.		
<b>Registrant notified that this is the last negotiation?</b> <u>___X___</u> Yes ___ submission was submitted and ___		
<b>Approve:</b> 		<b>Disapprove:</b>
<b>If disapproved, action to be taken:</b>		
<b>OD or DOD Signature:</b> 		<b>Date:</b> 11/28/08



Thomas C McEntee  
<Thomas.C.McEntee@usa.dupont.com>

11/26/2008 12:44 PM

To Linda Hollis/DC/USEPA/US@EPA

cc Raderrio Wilkins/DC/USEPA/US@EPA

bcc

Subject Re: Refined Oil of Nepeta cataria -- Renegotiated PRIA  
Action Dates to the calendar year 2009

Ms. Linda Hollis,

This will confirm the negotiated dates are in calendar year 2009 as you have  
detailed below.

Tom McEntee  
302 695 6856  
978 335 8055 CELL

Hollis.Linda@epamail.epa.gov

11/26/2008 12:07  
PM

To  
Thomas C McEntee/AE/DuPont@DuPont  
cc  
wilkins.raderrio@epa.gov

Subject  
Re: Refined Oil of Nepeta cataria  
-- Renegotiated PRIA Action Dates

Thank you, but there are some errors. The dates reflect year 2008. The  
dates should be the following:

71654-EN December 5, 2008

71654-EL and EU March 31, 2009

71654-EG and ER July 31, 2009 with the understanding that the Agency  
may likely to renegotiate again if the the Agency is not in receipt of  
all of the missing information, to include submission of the inert  
information to the Registration division by February 28, 2009.

Linda A. Hollis  
Chief, Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs (7511P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

hollis.linda@epa.gov  
(703) 308-8733 (phone)  
(703) 308-7026 (fax)  
Visit <http://www.epa.gov/pesticides>

Thomas C McEntee  
<Thomas.C.McEnte  
e@usa.dupont.com  
>

11/26/2008 12:00  
PM

To  
Linda Hollis/DC/USEPA/US@EPA  
cc  
Raderrio Wilkins/DC/USEPA/US@EPA  
Subject  
Refined Oil of Nepeta cataria --  
Renegotiated PRIA Action Dates

Ms. Linda Hollis,

This is to confirm our November 26, 2008 telephone conference regarding the need to renegotiate PRIA dates for the following applications for registration.

File Symbol	Product	Date	
71654-EN	Technical	December 5, 2008	(accomodate review of new active ingredient fact sheet)
71654-ER	15% Lotion	July 31, 2008	(acquire detail from inert supplier by Feb. 28, 2009 or further renegotiate)
71654-EG	7% Lotion	July 31, 2008	(same as 71654-EG)
71654-EL	15% Liquid	March 31, 2008	(resolve disconnect on acute toxicolgy series)
71654-EU	7% Liquid	March 31, 2008	(resolve disconnect on acute toxicolgy series from 71654-EL)
All			(re-review MRID 47362603 - Supplemental Efficacy Explanations; after the fact HSRB upgrades)

If you have any questions, please feel free to call or e-mail.

Thank you for your assistance with our application.

Enjoy the Thanksgiving Holiday.

Tom McEntee  
302 695 6856  
978 335 8055 CELL

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Raderrio  
Wilkins/DC/USEPA/US  
11/25/2008 09:46 AM

To Thomas C McEntee  
<Thomas.C.McEntee@usa.dupont.com>  
cc  
bcc  
Subject Re: Status report on the Technical (TGAI) application  
(71654-EN)

Dear Mr. McEntee

Please **addresses each individual Non-target requirement**. The guideline studies must be addressed with the submission of data or by submitting a request to waive the data requirement. A wavier request must be supported by a valid scientific rationale. The Agency letter dated November 13, 2008 Section III (3) provides a supporting argument from which you can build.

Sincerely,  
Raderrio Wilkins

Thomas C McEntee <Thomas.C.McEntee@usa.dupont.com>



Thomas C McEntee  
<Thomas.C.McEntee@usa.d  
upont.com>

11/24/2008 01:21 PM

To Raderrio Wilkins/DC/USEPA/US@EPA  
cc  
Subject Re: Status report on the Technical (TGAI) application  
(71654-EN)

Mr. Raderrio Wilkins,

(See attached file: 20081124 Nepeta Cover Non-Target Waiver.doc) (See attached file: 20081124 Non-Target Nepeta Tech Matrix.pdf)

Please let me know if this is sufficient of if you require something further.

Thanks,

Tom McEntee  
302 695 6856  
978 335 8055 CELL

Wilkins.Raderrio@  
epamail.epa.gov

11/21/2008 04:08  
PM

To  
Thomas C McEntee/AE/DuPont@DuPont  
cc  
wilkins.raderrio@eap.gov  
Subject  
Status report on the Technical  
(TGAI) application (71654-EN)

Dear Mr. Thomas McEntee,

Please refer to the attached document. If you have any questions, please contact me immediately.

(See attached file: scan.pdf)

Sincerely,

Raderrio Wilkins(See attached file: scan.pdf)

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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

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20081124 Nepeta Cover Non-Target Waiver.doc 20081124 Non-Target Nepeta Tech Matrix.pdf scan.pdf

Raderrio  
Wilkins/DC/USEPA/US

11/24/2008 03:10 PM

To Thomas C McEntee  
<Thomas.C.McEntee@usa.dupont.com>  
cc Raderrio Wilkins/DC/USEPA/US@EPA

bcc

Subject Re: Ethics

Dear Mr McEntee,

In response to your email dated Monday, November 24, 2008, please refer to EPA letter dated October 16 2007, Section IV that identified the data deficiencies associated with MRID 46977424, "Evaluation of the Efficacy of Personal Repellents against Mosquitoes in Florida" (MRID 46977425) and "Evaluation of the Efficacy of Personal Repellents against Blackflies in Maine" (MRID 47015602). DuPont responded to the study deficiencies by submitting a supplement (MRID 47362603) to the previously submitted unacceptable study. The supplement satisfactorily addressed the scientific deficiencies present in the original studies, however ethical issues still have not been resolved and may need further review (Classification remains unacceptable). Please refer to EPA faxed review dated 5/21/07 and courtesy follow up letter dated 11/13/08. In particular, ethical questions involve, but are not limited to:

- 1) The use of employees of Insect Control & Research in mosquito bite-testing,
- 2) The lack of monitoring information on local mosquito-borne vectors prior to testing,
- 3) Other issues identified in a previous review.

Sincerely  
Raderrio

Thomas C McEntee <Thomas.C.McEntee@usa.dupont.com>



Thomas C McEntee  
<Thomas.C.McEntee@usa.dupont.com>

11/24/2008 11:38 AM

To Raderrio Wilkins/DC/USEPA/US@EPA

cc

Subject Ethics

47362603 Hallahan, D. (2008) Supplement to "Evaluation of the Efficacy of Personal Repellents against Mosquitoes in Maine" (MRID 46977424), "Evaluation of the Efficacy of Personal Repellents against Mosquitoes in Florida" (MRID 46977425) and "Evaluation of the Efficacy of Personal Repellents against Blackflies in Maine" (MRID 47015602). Unpublished study prepared by E.I. duPont de Nemours and Company. 20 p. Trade Secret Status: Document Contains CBI Submitter: E.I. DUPONT DE NEMOURS AND COMPANY Submitter No. Submission Date Accession No. 071654 03/04/08 473626 03 Administrative No: 071654-20 Laboratory No.: 014663 INSECT CONTROL AND RESEARCH INC 071654 E.I. DUPONT DE NEMOURS AND COMPANY \*\*\* Chemistry Indexing \*\*\* SUBSTANCE CLASS: Single FORMULATION: Not Formulated Pesticide

Nepeta cataria oils (4801) \*\*\* Subject Indexing \*\*\* ROOT DT: 1035 Pesticide  
Use - Non-Pesticidal Use/Performance of Pesticides CONTENT CATEGORY:  
Complete Primary Report -- Experimental Research DT SITE: HUMAN BODY, HAIR,  
CLOTHING OR FOOTWEAR WHILE BEING WORN

Mr. Raderrio Wilkins,

The above submission was in response to the deficiencies stated in the  
efficacy review, which was forwarded in your October 2007 letter. I have  
not received any correspondence regarding the above study.

Thank you for your assistance with our applications.

Tom McEntee  
302 695 6856  
978 335 8055 CELL

Wilkins.Raderrio@  
epamail.epa.gov

11/13/2008 05:02  
PM

To  
Thomas C McEntee/AE/DuPont@DuPont  
cc  
Shah.Pv@epamail.epa.gov,  
Leifer.Kerry@epamail.epa.gov,  
Grinstead.Keri@epamail.epa.gov,  
Wilkins.Raderrio@epamail.epa.gov  
Subject  
Re: Status of Catnip Pending  
product applications

Dear Mr. Thomas McEntee,

Please refer to the attached document.

(See attached file: Catnip Deficiency letter 11.13.08.pdf)

Sincerely,  
Raderrio Wilkins

Thomas C McEntee  
<Thomas.C.McEnte  
e@usa.dupont.com  
>

11/05/2008 09:31

To  
Linda Hollis/DC/USEPA/US@EPA  
cc  
Raderrio Wilkins/DC/USEPA/US@EPA

AM

Subject  
Re: Status of Catnip Pending  
product applications

Ms. Linda Hollis,

Thank you for the e-mail. I look forward to the receipt of the  
deficiency  
letters.

I have been in contact with [REDACTED] after he was able to return to  
his  
office following Hurricane Ike.

I do expect to submit a renegotiated PRIA date for the formulations  
which  
you have been handling. I'll endeavor to detail the date at which we  
expect to submit the information on the inert or have it submitted  
directly  
to you.

Thank you for all of your efforts with the applications and successful  
completion of the technical grade product.

Tom McEntee  
302 695 6856  
978 335 8055 CELL

Hollis.Linda@epam

ail.epa.gov

To

10/31/2008 09:06

Thomas C McEntee/AE/DuPont@DuPont

AM

cc

wilkins.raderrio@epa.gov

Subject

Status of Catnip Pending product  
applications

Dear Mr. McEntee: I am providing to you the status of the Catnip pending applications. I do have good news and will provide that for you first. The technical product application will be registered by the prior due date of November 30, 2008. With regard to all of the he remaining end use products which will be formulated with TGAI material, they are deficient and will need to be renegotiated. For some time now there has been a serious issue with regard to one of the inert components in the formulations, i.e., the proprietary blend, the components of this blend unfortunately are not cleared. We have been in communication with you earlier this year and Karen Angulo did provide you with guidance as to how to proceed with the supplier of this blend. In fact, we do have record of contact with [REDACTED] who has provided us with information, but unfortunately, not what we need. Communication on the part of [REDACTED] did cease, and for that reason, we still are unable to process or clear the components of the blend. You will be receiving a detailed deficiency letter in the mail within the next week. However, I need to communicate to you your regulatory options. You will either need to renegotiate the due date for this products to be in line with how soon [REDACTED] will be able to make the formal request to the inerts branch as to what is needed and submit the information, in addition to addressing the data deficiencies that still remain with this products. Again, [REDACTED] is aware of what is needed and how to submit as told to him by EPA staff in the Inerts Branch. This information must come directly from the supplier. Should you not renegotiate and not make contact with the Agency, either myself or Mr. Wilkins, then we will proceed with the issuance of a can not grant letter by or on November 30, 2008. As explained to you in earlier letters, a can not grant letter will essentially put you out of a scheduled work frame, i.e., no longer prior. We can still work on your application, but there will be no scheduled time. Should you elect to renegotiate the date, keep in mind that Inert Clearance falls within the scope of the Registration Division. They have indicated that they will need four to five months to clear this inert, this time should be added to the amount of time that BPPD will need to conduct review (of the resubmitted information per the deficiency letter that is to come) and make a regulatory decision. Having said this, the total amount of renegotiated time will most likely be 8 months.

Your urgent response is requested.

Linda A. Hollis  
Chief, Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs (7511P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202  
hollis.linda@epa.gov  
(703) 308-8733 (phone)  
(703) 308-7026 (fax)  
Visit <http://www.epa.gov/pesticides>

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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

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[attachment "Catnip Deficiency letter 11.13.08.pdf" deleted by Thomas C McEntee/AE/DuPont]

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Raderrio  
Wilkins/DC/USEPA/US  
11/21/2008 04:01 PM

To Thomas C McEntee  
<Thomas.C.McEntee@usa.dupont.com>  
cc wilkins.raderrio@eap.gov

bcc

Subject Status report on the Technical (TGA) application  
(71654-EN)

Dear Mr. Thomas McEntee,

Please refer to the attached document. If you have any questions, please contact me immediately.



scan.pdf

Sincerely,  
Raderrio Wilkins



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

NOV 21 2008

DuPont Chemical Solutions Enterprise  
c/o Thomas C. McEntee  
P.O. Box 80402  
Wilmington, DE 1988-0402

Re: Application for a new Biochemical pesticide Registration  
Refined Oil of *Nepeta cataria*  
EPA File Symbol. No. 71654-EN (TGAI)

Dear Mr. McEntee:

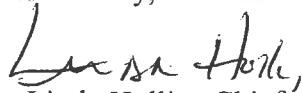
Your application for the technical product referenced above remains deficient and the Agency can not proceed with reviewing your application until you have adequately addressed the the Tier 1 Non-target Organisms and Environmental Fate data (158.2060) (refer to the Agency letter dated November 13, 2008, Section III (3)). DuPont Chemical Solutions Enterprise must submit a revised data matrix that addresses each individual Non-target requirement. The guideline studies must be addressed with the submission of data or by submitting a request to waive the data requirement. A wavier request must be supported by a valid scientific rationale. The Agency letter dated November 13, 2008 Section III (3) provides a supporting argument from which you can build.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for the action category (B60) of twelve months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, the PRIA due date precedes 75 day date and you will need to act quickly so the Agency can conduct our review and make a regulatory decision by PRIA decision date November 30, 2008. We will need the revised materials by November 25, 2008.

Alternately, you may renegotiate the due date for the product above, or withdraw the application and resubmit when you have all the information or the Agency will issue a can not grant letter under PRIA on or about November 30, 2008. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product immediately from the date of this letter at (703) 308-1259 with your response.

Sincerely,

A handwritten signature in cursive script, appearing to read "Linda Hollis".

Linda Hollis., Chief  
Biochemical Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

NOV 13 2008

DuPont Chemical Solutions Enterprise  
c/o Thomas C. McEntee  
P.O. Box 80402  
Wilmington, DE 1988-0402

Re: Application for a new Biochemical pesticide Registration  
Refined Oil of *Nepeta cataria*  
EPA File Symbol No.: 71654-EN (TGAI), -EG, -ER,  
PRIA Due Date November 30, 2008

Dear Mr. McEntee:

Please refer to my email dated May 28, 2008 and deficiency letter dated April 16, 2008. Your application remains deficient and we can not proceed with reviewing your application for the end use formulations with the inert clearance issue being unresolved. We renegotiated the PriA due dates for your products to reflect a date of November 30, 2008 with the understanding that you would address the "all" of the deficiencies identified in the Agency's letter dated October 16, 2007, along with submitting the materials necessary for the Inerts Branch to review and possibly resolve. BPPD was informed by Karen Angulo and Prakashcha Shah of the Inerts Branch that you have not submitted the requested information in a formal request or petition to have the inerts reviewed for clearance.

Therefore, your applications for Biopesticide registrations referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are not acceptable at this time. The Human Health Studies, however are acceptable and satisfy the tier 1 biochemical data requirements for the TGAI and End-Use products. The Product Chemistry and Product Performance data are **not acceptable** for the following reason(s):

**I. CSF**

**EPA File Symbol 71654-EG (7% Lotion)**

a. Provide a complete address and CAS registry number for the component [REDACTED]

b. Please change the CAS No. for [REDACTED]  
[REDACTED]

*follow-up letter  
to Mr. McEntee sent  
giving a status report.  
(refer to Linda Holli  
email dated 10/31/08  
R. L. [REDACTED]*

*also refer to email  
sent from R. L. [REDACTED]  
to Linda Holli  
on status  
dated  
9/30/08*

c. Please provide a CAS No. for the active ingredient.

d. [REDACTED]  
[REDACTED]  
[REDACTED] are not on the most recent on-line inert ingredients list (August 2004). Please provide alternate components that are on the EPA inert ingredients list or provide information to the inert ingredients branch (IIAB) for listing these (contact in IIAB - Kerry Leifer, leifer.kerry@epa.gov).

e. Please provide the chemical identities for [REDACTED]  
[REDACTED]  
[REDACTED] on the CSF.

f. Please address the discrepancy of why the content [REDACTED]  
[REDACTED] given on the CSF does not match the content given in MRID 47003301.

g. Please address the discrepancy of why the supplier for [REDACTED]  
[REDACTED] given on the CSF does not match the supplier given in MRID 47003301.

h. Please complete blocks 5. and 6. of the CSF.

**EPA File Symbol 71654-ER (15% Lotion)**

a. The same conditions and concerns reported for the 7% lotion (above) apply for the 15% lotion.

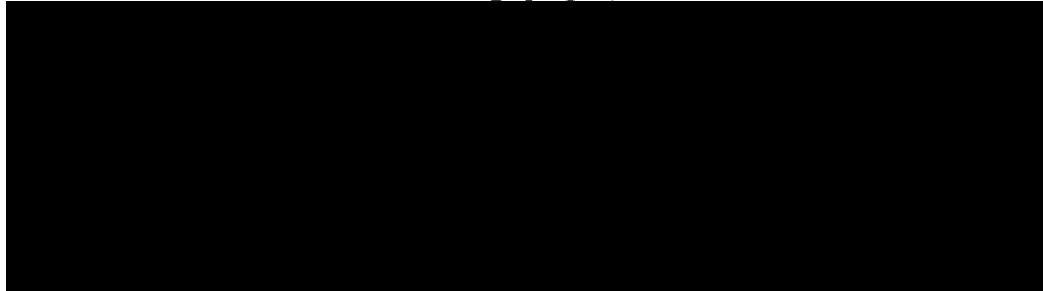
**II. PRODUCT CHEMISTRY**

**File Symbol 71654-EG (7% Lotion)**

- a. Please provide a rationale for the increase in percent weight of [REDACTED] in the 7% lotion when compared to the TGAI.
- b. Submit MSDSs or specification sheets for the all beginning materials, including those present as components in the mixtures.
- c. Submit quality control procedures for the formulation process.
- d. Please address the observation that extended storage at ambient conditions (25°C and 60% RH) results in the degradation of dihydronepetalactone and other components.

- e. Please submit information regarding the following inert ingredients (below) that are not on the most recent EPA inert ingredients list (August 2004).

BPPD recommends that the EPA inert ingredients branch (IIAB) be contacted for more information (contact in IIAB – Pv Shah, [Shah.Pv@epa.gov](mailto:Shah.Pv@epa.gov)).



**File Symbol 71654-ER (15% Lotion)**

- a. The same deficiencies outlined for the 7% lotion (above) apply for the 15% lotion.

**III. PHYSICAL PROPERTIES**

**File Symbol 71654-EG (7% Lotion)**

- a. Please address oxidation/reduction: chemical incompatibility and explosability.
- b. Submit storage stability and corrosion characteristics tests upon their completion.

**File Symbol 71654-ER (15% Lotion)**

- a. The same deficiencies outlined for the 7% lotion (above) apply for the 15% lotion.

2. Tier I Toxicity studies are **ACCEPTABLE**.

3. Tier I Non-Target studies have not been submitted by the registrant. EPA expects that the use pattern of this product as an insect repellent will preclude significant adverse exposure to nontarget organisms. Please address the data requirements by submitting data or a request to waive the data requirement (the data matrix must reflect this request along with MRIDs and rationale for waiving).

**IV. PRODUCT PERFORMANCE**

- a. Please provide detailed discussion on the statistics employed to analyze the data.

- b. Please address the inconsistencies concerning the amount of test material applied to subjects.
- c. It is not clear whether the landing rates for the whole body counts are based on 1 minute exposure taken for 1. This information regarding landing rates must be noted in the results table (Appendix IV).
- d. The test sites were not monitored for incidences of mosquito-borne disease prior to testing.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for the action category (B60) of twelve months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, there is not enough time remaining before the PRIA decision date of November 30, 2008 for you to submit the information requested above and for BPPD to complete the review and make a regulatory decision. The deficiencies outlined above for the three end use products in addition to review and clearance of the inert ingredients contained in the proprietary blend will require EPA review and regulatory decision making of 8 months post the date that the information is resubmitted to the Agency.

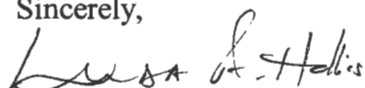
Therefore, you may renegotiate the due dates for the three products above, or withdraw the applications and resubmit when you have all the information or the Agency will issue a can not grant letter under PRIA on or about November 30, 2008. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product immediately from the date of this letter at (703) 308-1259 with your response. Again, we will require an extension time of 8 months post the date that you expect to make a full resubmission of the information. We can not renegotiate the date based on a partial submission. You should allow yourself adequate time for your supplier of the proprietary blend to make the submission (officially) to the Agency in addition to enough time for Dupont to address the above the deficiencies. We must have confirmation of a renegotiated due date from you via email by the close of business on November 20, 2008.

As stated above, the request for clearance of the components in the proprietary blend must be submitted to the Agency from the supplier. The EPA has communicated with your supplier and has indicated what information the Agency will need. Given that this information is confidential, we can tell you that the request must be officially submitted to the Agency to the attention of the Inerts Branch of the Registration Division. The request will be for a petition and must state so. The request or formal submission must petition the Agency for food or non food clearance and must contain the components and amount in the blend. Once received and deemed sufficient, this request for clearance will be scheduled. I strongly suggest that you coordinate the

timing of this submission and the submission which will address the above product chemistry issues. Again, partial submissions will not be considered.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda A. Hollis". The signature is fluid and cursive, with the first name "Linda" being more prominent.

Linda A. Hollis., Chief  
Biochemical Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)

CC:

Pv Shah

Kerry Leifer



Thomas C McEntee  
<Thomas.C.McEntee@usa.dupont.com>

11/05/2008 09:31 AM

To Linda Hollis/DC/USEPA/US@EPA  
cc Raderrio Wilkins/DC/USEPA/US@EPA

bcc

Subject Re: Status of Catnip Pending product applications

Ms. Linda Hollis,

Thank you for the e-mail. I look forward to the receipt of the deficiency letters.

I have been in contact with [REDACTED] after he was able to return to his office following Hurricane Ike.

I do expect to submit a renegotiated PRIA date for the formulations which you have been handling. I'll endeavor to detail the date at which we expect to submit the information on the inert or have it submitted directly to you.

Thank you for all of your efforts with the applications and successful completion of the technical grade product.

Tom McEntee  
302 695 6856  
978 335 8055 CELL

Hollis.Linda@epamail.epa.gov

10/31/2008 09:06 AM

To  
Thomas C McEntee/AE/DuPont@DuPont  
cc  
wilkins.raderrio@epa.gov  
Subject  
Status of Catnip Pending product applications

Dear Mr. McEntee: I am providing to you the status of the Catnip pending applications. I do have good news and will provide that for you first. The technical product application will be registered by the pria due date of November 30, 2008. With regard to all of the he remaining end use products which will be formulated with TGA material, they are deficient and will need to be renegotiated. For some time now there has been a serious issue with regard to one of the inert components in the formulations, i.e., the proprietary blend, the components of this blend unfortunately are not cleared. We have been in communication with you earlier this year and Karen Angulo did provide you with guidance as to

how to proceed with the supplier of this blend. If fact, we do have record of contact with [REDACTED] who has provided us with information, but unfortunately, not what we need. Communication on the part of [REDACTED] did cease, and for that reason, we still are unable to process or clear the components of the blend. You will be receiving a detailed deficiency letter in the mail within the next week. However, I need to communicate to you your regulatory options. You will either need to renegotiate the due date for this products to be in line with how soon [REDACTED] will be able to make the formal request to the inerts branch as to what is needed and submit the information, in addition to addressing the data deficiencies that still remain with this products. Again, [REDACTED] is aware of what is needed and how to submit as told to him by EPA staff in the Inerts Branch. This information must come directly from the supplier. Should you not renegotiate and not make contact with the Agency, either myself or Mr. Wilkins, then we will proceed with the issuance of a can not grant letter by or on November 30, 2008. As explained to you in earlier letters, a can not grant letter will essentially put you out of a scheduled work frame, i.e., no longer pria. We can still work on your application, but there will be no scheduled time. Should you elect to renegotiate the date, keep in mind that Inert Clearance falls within the scope of the Registration Division. They have indicated that they will need four to five months to clear this inert, this time should be added to the amount of time that BPPD will need to conduct review (of the resubmitted information per the deficiency letter that is to come) and make a regulatory decision. Having said this, the total amount of renegotiated time will most likely be 8 months.

Your urgent response is requested.

Linda A. Hollis  
Chief, Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs (7511P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202  
hollis.linda@epa.gov  
(703) 308-8733 (phone)  
(703) 308-7026 (fax)  
Visit <http://www.epa.gov/pesticides>

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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

Raderrio  
Wilkins/DC/USEPA/US

09/30/2008 06:15 PM

To Linda Hollis/DC/USEPA/US@EPA

cc

bcc

Subject The status on the Catnip Products (71654-EG, ER, EU and EL)

Linda,

Per your request, I summarized the status of the Catnip products for your information (details listed below).

**EPA File Symbol 71654-EN (TGAI):**

1. The registrant addressed the Product chemistry for the TGAI in MRIDs (47362601 and 47362602).
2. The registrant must submit storage stability and corrosion characteristics tests.
3. The Tier I Toxicity studies have previously been termed **ACCEPTABLE** (Gardner to Wilkins 10/04/07; Wilkins to McEntee 10/16/07). DuPont submitted a discussion (MRID 47362604) that addressed the questions EPA had regarding a positive mouse lymphoma assay. The discussion provided an **ACCEPTABLE** rationale for the TGAI being non-genotoxic and explores the concept of false test positives and weight of the evidence.
4. Although product performance data is not required for the registration of the TGAI (Refined oil of *Nepeta cataria* ), however DuPont responded to the study deficiencies by submitting a supplement (MRID 47362603) to the previously submitted **UNACCEPTABLE** study. **The supplement satisfactorily addressed the scientific deficiencies present in the original studies, however ethical issues still have not been resolved and may need further review (Classification remains UNACCEPTABLE, but upgradable).**  
In particular, ethical questions involve, but are not limited to:
  - 1) The use of employees of Insect Control & Research in mosquito bite-testing,
  - 2) The lack of monitoring information on local mosquito-borne vectors prior to testing,
  - 3) Other issues identified in a previous review (Fuentes to Wilkins 10/04/07).

**EPA File Symbol 71654-ER and EG (EPs):**

1. Product chemistry and CSF deficiencies for the 7% (71654-EG) and 15% (71654-ER) lotion have not been addressed as requested (Wilkins to McEntee, 10/16/07). I am not in receipt of any resubmission for products **71654-ER, EG, EU or EL.**

Sincerely,  
Raderrio

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460**

**OFFICE OF PESTICIDES AND TOXIC SUBSTANCES**

**MEMORANDUM**

**DATE:** August 12, 2008

**SUBJECT:** Response to Deficiencies in Support of the Registration of the Refined Oil of  
Nepeta Cataria (TGAI)

**Decision Number:** 371861

**DP Number:** 351625

**EPA File Symbol Number:** 71654-EN

**Chemical Class:** Biochemical

**PC Code:** 004801

**CAS Number:** 490-09-5 (dihydronepetalactone)

**Active Ingredient Tolerance Exemptions:** None

**MRID Numbers:** 47370401, 47362602, 47362603, 47362604

**FROM:** Kent R Carlson, PhD, Biologist  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511P)

**TO:** Raderrio Wilkins, Regulatory Action Leader  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511P)

**\*\*\*\*\* CONTAINS CONFIDENTIAL BUSINESS INFORMATION \*\*\*\*\***

**ACTION REQUESTED**

E.I. du Pont de Nemours and Company has submitted a response to deficiencies for the TGAI "Refined Oil of Nepeta cataria" (71654-EN) as presented in a letter from Hollis to MEntee (10/16/07). The TGAI is intended for use in the manufacture of a dermally applied insect repellent. In support of the registration of the TGAI, the registrant has submitted product chemistry (MRIDs 47362601 and 47362602), efficacy (MRID 47362603), and toxicology (MRID 47362604) data. These studies have been briefly reviewed in this memo.

## RECOMMENDATIONS AND CONCLUSIONS

**NOTE TO RAL:** Some of the product chemistry certified limits are dependent on the previous information submitted for the EP (ie 2f, 2h, 2i). While a minor consideration, the decision for acceptable TGAI certified limits may be altered if the end-use products are altered substantially (such that the components mentioned become detectable in the EP)

1. Product chemistry and CSF deficiencies for the 7% (71654-EG) and 15% (71654-ER) lotion have not been addressed as requested (Hollis to McEntee, 10/16/07). *no*

2. Product chemistry for the TGAI (MRIDs 47362601 and 47362602) has been addressed. *yes*

a. The registrant has submitted CAS Registry numbers for all ingredients on the CSF and placed these after the component descriptor *as requested by EPA*. *OK*

b. The registrant has listed impurities present on a previous CSF (10/12/06; [REDACTED]) on the revised CSF (02/28/08) and has provided documentation of the minor constituents and their hydrogenation products ("other ingredients") expected to be found in the Refined oil of *Nepeta cataria* (MRID 47362602, review below).

*4*  
EPA previously asked the registrant to present additional minor constituents on the CSF, but realizes that presentation of these numerous impurities and their hydrogenated forms on the CSF would add little regulatory value, since they are not of toxicological significance and are in small/highly variable quantities. For this reason, EPA expects that ***presentation in the submitted MRID (47362602) is ACCEPTABLE*** and will fulfill the intent of identifying critical components/molecules in the Refined oil of *Nepeta cataria* distilled plant extract. The Registrant must add "(see MRID 47362602)" to immediately after the component "Other ingredients" in block 10 of the CSF to account for this. *DIL*

c. The information on the top row of the CSF where refined oil of *Nepeta cataria* is identified as "active technical grade" has been deleted *as requested by EPA*. *OK*

d. The parentheses around the amounts of the remaining ingredients provided in column 13b of the CSF have been deleted *as requested by EPA*. *OK*

e. The identity of the active ingredients given on the CSF and the product label have been made consistent *as requested by EPA*. *OK*

f. The registrant has based certified limits on *recommendations from EPA* that [REDACTED] would be sufficient for regulatory purposes. The former group brackets concentrations found in both the first and second preliminary analysis performed by Exygen and DuPont. The latter group

\*Manufacturing process information may be entitled to confidential treatment\*

has been extracted from the preliminary analysis. EPA considers this range satisfactory for regulatory purposes because the component is undetectable in the final EP products.

g. The lower certified limits for impurities, unreacted starting materials, etc. has been deleted *as requested by EPA*.

h. The proposed upper certified limit for [REDACTED] has been altered to reflect the upper part of the range described in preliminary analyses [REDACTED] *as requested by EPA*. EPA considers this satisfactory for regulatory purposes because the component is undetectable in the final EP products.

i. The proposed upper certified limit for [REDACTED] has been altered to reflect the upper part of the range described in preliminary analyses [REDACTED] *as requested by EPA*. EPA considers these upper limits to be satisfactory, considering the variation present in source material supply, source material composition, the negligible amount of these components in EP products, [REDACTED] and the anticipation that no additional toxicity (other than that already associated with dihydronepetalactone) will be associated with these components.

j. Following the addition of other ingredients to the CSF, the registrant has ensured that the % by weight total = 100% *as requested by EPA*.

k. The registrant has completed blocks 5. and 6. of the CSF *as requested by EPA*.

### 3. Physical Properties for the TGAI (MRID 47370401)

a. The registrant has addressed explodability *as requested by EPA*.

b. **The registrant must submit storage stability and corrosion characteristics tests upon their completion.**

c. The registrant has addressed stability in the presence of different temperatures and metals by discussing the relative impacts that packaging and storage will have on the stability of the product *as requested by EPA*.

d. The registrant has provided a method for the determination of density *as requested by EPA*.

4. Tier I Toxicity studies have previously been termed **ACCEPTABLE** (Gardner to Wilkins 10/04/07; Hollis to McEntee 10/16/07). Even so, DuPont has submitted a discussion (MRID 47362604) that addresses questions EPA had regarding a positive mouse lymphoma assay (review below). This discussion provides **ACCEPTABLE** rationales for the TGAI being non-genotoxic and explores the concept of false test positives and weight of the evidence.

5. Product Performance data have been previously termed **UNACCEPTABLE, but Upgradable** (Fuentes to Wilkins 10/04/07). DuPont has responded to study deficiencies by submitting a supplement (MRID 47362603) to the previous study. *The supplement has satisfactorily addressed the scientific deficiencies present in the original studies. Ethical issues have still not been resolved however, and may need further review (Classification remains UNACCEPTABLE, but upgradable).* In particular, ethical questions involve, but are not limited to:

- 1) The use of employees of Insect Control & Research in mosquito bite-testing,
- 2) The lack of monitoring information on local mosquito-borne vectors prior to testing,
- and 3) other issues identified in a previous review (Fuentes to Wilkins 10/04/07).

**NOTE TO RAL: Product performance data is not required for the registration of the TGA1 (Refined oil of *Nepeta cataria*). This data is only required for Typical End-use Products associated with pests of public health importance (in this case, mosquitoes and black flies).**

### **Endangered Species Assessment**

Two rationales support a **Not Likely to Adversely Affect** (NLAA) decision for the TGAI, Refined Oil of *Nepeta cataria*. These are discussed below.

1) No target or non-target biotic exposure (target or non-target) is expected to result from the manufacture and integration of the TGAI into formulated products.

2) EPA has previously established that Chrysopidae (lacewings) may be adversely impacted by dihydronepetalactone, a molecular component in the Refined Oil of *Nepeta cataria* (Carlson to Wilkins, 10/04/07). To address concerns related to endangered Chrysopidae, EPA has retrieved a list of Chrysopidae (lacewings) from Natureserve (<http://www.natureserve.org/explorer/index.htm>; *Lomamyia banksi*, *Lomamyia flavicornis*, *Nallachius americanus*, *Nothochrysa californica*, *Oliarces clara*, *Polystoechotes punctatus*, *Symphorobius occidentalis*) and cross-referenced these with threatened and endangered listings posted with the US Fish and Wildlife Service (USFWS; [http://ecos.fws.gov/tess\\_public/StartTESS.do](http://ecos.fws.gov/tess_public/StartTESS.do)) and LOCATES (OPP-EFED v. 2.1, March 2006). No species of either lacewings or aphids have been listed as threatened or endangered, so no concerns exist for these particular insects.

## STUDY REVIEWS

**MRID 47370401** - Supplement to Preliminary Analysis Physical and Chemical Characteristics: In this volume, DuPont re-iterated that deficiencies previously identified with the CSF could be identified point-by-point on the CSF. DuPont further addressed deficiencies associated with "PHYSICAL PROPERTIES". These are identified below and appended to the attached table (Table 1):

**a) Explodability** - DuPont has identified that the Refined Oil of *Nepeta cataria* has a flashpoint of between 140 and 200°F, is a Class IIIA combustible liquid, and has a very limited potential for explosion hazard.

**b) Storage Stability and Corrosion Characteristics** - DuPont has stated that these "are addressed in a separate study", but has not identified which study, the completion date or other evidence for review (other than the 14-day results originally submitted). These studies should be submitted upon completion.

**c) Stability in the Presence of Metals and Ions** - DuPont has reported that the Refined Oil of *Nepeta cataria* is stable in the presence of metals and ions. Even so, it will be stored and packaged in High Density Polyethylene containers to minimize such exposures.

**d) Density** - DuPont has submitted that density measurements (non-GLP) were performed by using a calibrated Mettler Toledo Densito 30PX instrument with automatic temperature correction.

**Table 1. Physical and Chemical Properties for Refined Oil of *Nepeta cataria***

Guideline Reference No./Property	Description of Result	Methods
830.6302 Color	Yellow @ 21°C	CCL SOP 10.11
830.6303 Physical State	Liquid @ 21°C	CCL SOP 10.12
830.6304 Odor	Minty @ 21°C	CCL SOP 10.13
830.6313 Stability	Stable @ room and elevated temperatures and in the presence of metals and ions	OPPTS 830.6313
830.6314 Oxidation/Reduction: Chemical Incompatibility	Dihydronepetalactone was relatively stable in solution with metals and metal salts after 14 days at 25°C, with slight decreases at 54°C after 14 days.	Multiple
830.6315 Flammability	>99°C (flashpoint between 140°F and 200°F)	CCL SOP 10.18; ASTM Method No. D56 (Closed Cup)
830.6316 Explodability	Not explosive (Class IIIA combustible liquid)	N/A
830.6317 Storage Stability	At 25 °C dihydronepetalactone content was relatively stable. At 54°C, dihydrocontent decreased approximately 5-10% over a 2 week period. Al, Fe, Al acetate, and Iron (II) acetate had minimal effects.	Gas Chromatography
830.6319 Miscibility	Not applicable, product is not to be diluted in petroleum solvents	N/A
830.6320 Corrosion Characteristics	Guideline study is in progress	Pending
830.6321 Dielectric Breakdown Voltage	Not applicable, product is not for use around electrical equipment	N/A
830.7000 pH	3.97 @ 25°C (1% w/w in deionized water)	CCL SOP 10.17; ASTM Method No. E70
830.7050 UV/Visible Absorption	Not applicable	N/A
830.7100 Viscosity	18.09 mm <sup>2</sup> /s (cSt) @ 22°C	ASTM D 445 and D446
830.7200 Melting Range	Not applicable, product is a liquid	N/A
830.7220 Boiling Range	266.0 ± 12.0°C (539.2K)	Mettler FP900 Thermosystem
830.7300 Density/Relative Density/Bulk Density	1.0349 @ 20.6°C	Mettler Toledo Densito 30PX instrument (oscillating body method)
830.7370 Dissociation Constant in Water	Not applicable, required only for pure active ingredient	N/A
830.7550 Partition Coefficient	Not applicable, required only for pure active ingredient	N/A
830.7840 Water Solubility	0.254 ± 0.013 g/L @ "ambient temperature"	OPPTS 7840 Gas chromatograph
830.7950 Vapor Pressure	591, 707, 907, 1100, 1320, and 1630 Pa @ 20, 25, 30, 35, and 40°C, respectively	Terranova 722A diaphragm gauge controller

**MRID 47362602** - Supplement: Prediction of minor constituents of Refined oil of *Nepeta cataria* as likely hydrogenation products. In this volume, DuPont summarized *Nepeta cataria* oil composition data from seven oil sources (in five reports). Molecular structures of the compounds and their proposed hydrogenated forms were also provided.

Data from the seven plant accessions were averaged, with “-” and “t” counted as 0.0. These averages are presented below in Table 2:

<b>Table 2. Average % Composition for Minor Components in Extracts of <i>Nepeta cataria</i></b>			
Compound (CAS Number)	Average % composition	Compound (CAS Number)	Average % composition
Trans,trans-nepetalactone (490-10-8)	<0.1	Caryophyllene oxide (1139-30-6)	4.87
2,6-dimethyl-2,5-heptadien-4-one (504-20-1)	<0.1	Dihydronepetalactone (490-09-5)	4.53
2-methyl-2,3-dihydroindole (?; 6872-06-6)	<0.1	Cis,cis-nepetalactone (490-10-8)	2.6
Nepetalactam	<0.1	$\alpha$ -humulene (6753-98-6)	1.11
3-hexenyl benzoate (72200-74-9)	<0.1	Nepetalic acid (4581-78-6; 75110-45-1)	0.4
Nonanoic acid (112-05-0)	<0.1	E- $\beta$ -farnesene (502-61-4)	0.4
Dihydroactinidiolide (17092-92-1)	<0.1	Humulene oxide (19888-33-6)	0.39
Iridomyrmecin/isoiridomyrmecin (485-43-8)	<0.1	Piperitone (89-81-6)	0.37
Germacrene D (23986-74-5)	<0.1	3-hexenyl ester (105583-82-2)	0.3
(Z)- $\beta$ -ocimene (13877-91-3)	<0.1	Myrcene (123-35-3)	0.21
(E)- $\beta$ -ocimene (13877-91-3)	<0.1	$\beta$ -elemene (723296-74-0)	0.2
1,8-cineole (470-82-6)	<0.1	Thymol methyl ester (1076-56-8)	0.19
Limonene (138-86-3)	<0.1	Dehydronepetalactone	0.14
Trans,cis-nepetalactone (490-10-8)	42.21	Dimethyl-3,7-oxa-1-bicyclo[3,3,0]oct-2-ene (389599-94-4)	0.14
Cis,trans-nepetalactone (490-10-8)	41.19	Camphor (76-22-2)	0.11
$\beta$ -caryophyllene (87-44-5)	6.43		

Data from the molecular structures section of the discussion (p12-47) were tabulated to compare the extract component and the most likely hydrogenation product. These are presented below in Table 3:

Table 3. <i>Nepeta cataria</i> Components and Likely Hydrogenation Products			
Compound (CAS Number)	Likely Hydrogenated Compound (CAS Number)	Compound (CAS Number)	Likely Hydrogenated Compound (CAS Number)
Trans,trans-nepetalactone (490-10-8)		Caryophyllene oxide (1139-30-6)	4,9,12,12-tetramethyl-5-oxatricyclo[8.2.0.0.4,6]dodecane (1209-61-6)
2,6-dimethyl-2,5-heptadien-4-one (504-20-1)	2,6-dimethyl-4-heptanone (108-83-8)	Dihydronepetalactone (490-09-5)	Dihydronepetalactone (490-09-5)
2-methyl-2,3-dihydroindole (?; 6872-06-6)	2-methyl-2,3-dihydroindole (6872-06-6)	Cis,cis-nepetalactone (490-10-8)	
Nepetalactam		$\alpha$ -humulene (6753-98-6)	
3-hexenyl benzoate (72200-74-9)	Benzoic acid hexyl ester (6789-88-4)	Nepetalic acid (4581-78-6; 75110-45-1)	
Nonanoic acid (112-05-0)	Nonanoic acid (112-05-0)	E- $\beta$ -farnesene (502-61-4; 125037-13-0)	2,6,10-trimethyl-dodecane (3891-98-3)
Dihydroactinidiolide (17092-92-1)		Humulene oxide (19888-33-6)	
Iridomyrmecin/isoiridomyrmecin (485-43-8)	Iridomyrmecin/isoiridomyrmecin (485-43-8)	Piperitone (89-81-6)	(2R)-5-methyl-2-(1-methylethyl)-cyclohexanone (188002-55-3)
Germacrene D (23986-74-5317819-88-8)	1,7-dimethyl-4-(1-methylethyl)-cyclodecane stereoisomer (645-10-3)	3-hexenyl ester (105583-82-2)	
(Z)- $\beta$ -ocimene (13877-91-3)	2,6-dimethyloctane (2051-30-1)	Myrcene (123-35-3)	2,6-dimethyloctane (2051-30-1)
(E)- $\beta$ -ocimene (13877-91-3)	2,6-dimethyloctane (2051-30-1)	$\beta$ -elemene (723296-74-0)	1-ethyl-2,4-diisopropyl-1-methyl-cyclohexane (1756-79-2)
1,8-cineole (470-82-6)	1,8-cineole (470-82-6)	Thymol methyl ether (1076-56-8)	Thymol methyl ether (1076-56-8)
Limonene (138-86-3)	1-methyl-4-(1-methylethyl)-cyclohexane (99-82-1)	Dehydronepetalactone	
Trans,cis-nepetalactone (490-10-8)		Dimethyl-3,7-oxa-1-bicyclo[3,3,0]oct-2-ene (389599-94-4)	[3R-(3 $\alpha$ ,3 $\beta$ ,6 $\beta$ ,6 $\alpha$ )]-hexahydro-3,6-dimethyl-1(2H)-pentalenone (120709-97-9)
Cis,trans-nepetalactone (490-10-8)		Camphor (76-22-2)	Camphor (76-22-2)
$\beta$ -caryophylline (87-44-5)	4,9,12,12-tetramethyl-5-oxatricyclo[8.2.0.0.4,6]dodecane (1209-61-6)		

**MRID 47362603** - Supplement to "Evaluation of the efficacy of personal repellents against mosquitoes in Maine" (MRID 46977424), "Evaluation of the efficacy of personal repellents against mosquitoes in Florida" (MRID 46977425) and "Evaluation of the efficacy of personal repellents against blackflies in Maine" (MRID 47015602). In this volume, DuPont has responded to product performance deficiencies reported previously (Fuentes to Wilkins, May 21, 2007). These deficiencies were listed under **IV PRODUCT PERFORMANCE** as:

a. The registrant has provided detailed discussion on the statistics employed to analyze the data. DuPont used an ANOVA derived from statistical software (GraphPad Prism v.4) to analyze repellency in terms of active ingredient concentration and formulation type. The two-way analyses determined that active ingredient concentration effects were statistically different for both mosquitoes and blackflies and the formulation type effects were different for mosquitoes (Table 4).

<b>Table 4. ANOVA Addressing Active Ingredient Concentration and Formulation Type Effects</b>			
Insect	Source of Variation	% of Total Variation	P value
Mosquito	Interaction	6.13	0.0251*
Mosquito	Formulation	21.43	<0.0001***
Mosquito	Active Ingredient Concentration	12.86	0.0015**
Blackfly	Interaction	2.12	0.2455 <sup>ns</sup>
Blackfly	Formulation	2.41	0.2159 <sup>ns</sup>
Blackfly	Active Ingredient Concentration	10.56	0.0112*
*** = extremely significant, ** = very significant, * = significant, ns = not significant			

Descriptive statistics (GraphPad Prism v.4) were also used in order to describe field test results (complete protection time in minutes). Mean complete protection times against mosquitoes averaged 4 hours 17 minutes (7% liquid), >6 hours 43 minutes (7% lotion), 6 hours 25 minutes (15% liquid), and >7 hours 7 minutes (15% lotion). Mean complete protection times against blackflies averaged >5 hours 59 minutes (7% liquid), >6 hours 59 minutes (7% lotion), >7 hours 32 minutes (15% liquid), and >7 hours 34 minutes (15% lotion) (p15). The descriptive statistics are presented in Table 5 and 6.

<b>Table 5. Complete Protection Time for the 7% Formulations as Assessed by Descriptive Statistics</b>								
	7% Lotion				7% Liquid			
	FL-mosquito	ME-mosquito	ME-black fly	ME-black fly	FL-mosquito	ME-mosquito	ME-black fly	ME-black fly
N	5	5	5	5	5	5	5	5
Minimum	270	410	338	139	192	27	327	121
25%ile	276	413	344	310	221	151	347	146
Median	282	480	480	480	252	288	476	213
75%ile	469	480	480	480	297	347	480	480
Maximum	480	480	480	480	324	347	480	480
Mean	354	453	425	412	257	257	426	293
StdDev	105	37	75	152	47	132	74	174
Std Error	47	17	33	68	21	59	33	78
Lower 95% CI	224	407	332	222	199	92	335	77
Upper 95% CI	485	499	518	601	316	421	517	509

Normality P value	>0.10	>0.10	>0.10	>0.10	>0.10	>0.10	>0.10	>0.10
Passed normality test? ( $\alpha=0.05$ )	yes	yes	yes	yes	yes	yes	yes	yes
Skewness	0.30	-0.30	-0.30	-1.1	0.032	-0.91	-0.37	0.22
Kurtosis	-2.2	-2.2	-2.2	-0.92	-1.5	-1.1	-2.1	-2.2

**Table 6. Complete Protection Time for the 15% Formulations as Assessed by Descriptive Statistics**

	15% Lotion				15% Liquid			
	FL-mosquito	ME-mosquito	ME-black fly	ME-black fly	FL-mosquito	ME-mosquito	ME-black fly	ME-black fly
N	10	10	10	10	10	10	10	10
Minimum	309	480	318	335	281	306	360	177
25%ile	320	480	418	458	295	451	444	448
Median	341	480	476	480	307	480	480	480
75%ile	461	480	480	480	331	480	480	480
Maximum	480	480	480	480	362	480	480	480
Mean	374	480	447	461	314	457	461	443
StdDev	68	0.0	52	46	24	56	38	95
Std Error	22	0.0	17	15	7.5	18	12	30
Lower 95% CI	325	480	409	428	297	417	433	375
Upper 95% CI	422	480	484	494	331	497	488	511
Normality P value	>0.10	-	>0.10	0.03	>0.10	0.0287	0.09	>0.10
Passed normality test? ( $\alpha=0.05$ )	yes	-	yes	no	yes	no	yes	yes
Skewness	0.61	0.0	-1.4	-2.0	0.54	-1.9	-1.7	-2.2
Kurtosis	-1.5	0.0	0.77	2.4	-0.78	2.3	1.8	3.2

Landings per count interval were also displayed graphically for each untreated subject (p10, p12, p13). Graphs indicated relatively constant to increasing landing pressure over time.

b. The registrant has addressed the inconsistencies concerning the amount of test material applied to subjects. Reported amounts of applied test materials are as follows in Table 7.

<b>Table 7. Application of Test Material to Subjects</b>				
Units	7% Lotion	7% Liquid	15% Lotion	15% Liquid
mg/cm <sup>2</sup>	2.56	1.60	2.52	1.61
g/600cm <sup>2</sup>	1.536	0.960	1.512	0.966
mg/m <sup>2</sup>	1792	1116	3780	2412
OPPTS 810.3700 rec. values (g/600cm <sup>2</sup> )	1.50	1.0	1.50	1.0

c. It is not clear whether the landing rates for the whole body counts are based on 1 minute exposure taken for 1. This information regarding landing rates must be noted in the results table (Appendix IV).

The registrant has provided information regarding the landing rates for the efficacy tests. The treated subjects were exposed to mosquitoes or black flies and watched for 8 hours or until it was judged the repellent had broken down (first of two mosquito bites, or 2 second duration blackfly landings occurring within 30 minutes of each other).

Landing rates on **skin patches** for untreated subjects were taken for 5 minute durations every 30 minutes. The number of mosquitoes or black flies on the untreated person's **body** was also counted for 1 minute durations every hour.

d. The test sites were not monitored for incidences of mosquito-borne disease prior to testing. The registrant has provided additional information regarding the potential for mosquito and blackfly-borne diseases. These factors illustrate the low probability for contracting mosquito or black fly-bourne diseases and that if such occurred, the workers would be covered medically. The rationales for maintaining human safety in this study were as follows:

- 1) Each subject gave Informed Consent.
- 2) Each subject was covered in entirety from biting insects, except for the open testing skin patches.
- 3) Black fly tests were considered completed after landings, not bitings.
- 4) Mosquito tests were considered completed after 2 mosquito bites within 30 minutes of each other (so the potential total number of bites per day was marginal).
- 5) Exposure protocols were cleared through DuPont's Human Studies Review Board and an external Institutional Review Board (non-EPA).
- 6) Each subject's shoes were treated with Permanone® to discourage tick attachment while in the field.
- 7) There had been no reported human cases of West Nile Virus (WNV) in Maine as of the date of testing.
- 8) *Culex* spp. mosquitoes (WNV carriers) are uncommon in Maine near the study sites.
- 9) *Ochlerotatus intrudens* was the only positively identified mosquito in the Maine field trial. This mosquito has not been identified as a WNV carrier by the CDC.
- 10) *Culex* spp. mosquitoes are uncommon at the Florida site.
- 11) Potential WNV carrier species including *Psorophora ferox*, *Ochlerotatus atlanticus/tormentor*, *Ochlerotatus taeniorhynchus*, and *Culiseta melanura* were present throughout the FL tests.
- 12) The potential WNV carrier *Culex iolambdis* was present only late in the study, so probably contributed little to the bite pressure.
- 13) The subjects were employees of Insect Control & Research and so were covered by Workman's Compensation if medical problems occurred.

**MRID 47362604** - Response from DuPont to the U.S. EPA Genetic Toxicity Recommendation in "Science Review and Human Health Risk Assessment in Support of the Registration of the Insect Repellent Refined Oil of *Nepeta cataria* (TGAI), and two lotion end-use products": DuPont has voluntarily submitted a response to EPA concerns regarding a positive mouse lymphoma test (MRID 46977413) and identified potential mitigating circumstances inherent in the study design and proposed a weight of evidence decision for overall effect categorization.

A single positive response was observed in the *In Vitro* Mammalian Cell Gene Mutation Test (L5178Y/TK+/-Mouse Lymphoma Assay (MLA; OPPTS 870.5300; MRID 46977413). EPA recommended that the registrant confirm this result with an additional assay in a mammalian cell system and/or discuss the significance of the positive finding.

In the rebuttal, DuPont proposed that the four submitted studies were sufficient to address the mutagenic properties of the TGAI, concurred with the assessment that there was "clear evidence of induced mutant colonies over background", but disagreed with the conclusion that this created a genetic toxicology data gap. DuPont further supported this line of reasoning by pointing out that:

- 1) the positive response in the MLA was observed at doses approaching cytotoxicity (mutagenicity secondary to cytotoxicity),
- 2) the frequency of small colonies was increased in the MLA test, suggesting that point mutations or deletions were occurring in the TK locus. Point mutations or deletions were not, however, observed in the other *in vitro* tests at comparable doses and conditions (non-reproducible non-confirmable effect),
- 3) the negative *in vitro* results were confirmed by an *in vivo* mouse micronucleus assay, in which the dose induced adverse systemic effects (decrease in frequency of polychromatic erythrocytes), which suggested that the compound was tested at an appropriate limit dose and was reaching the target site,
- 4) the high frequency of false positives for the MLA test,
- and 5) the lack of structural or biochemical properties in the TGAI that would be associated with genotoxicity.

When considered in toto, the weight of evidence presented suggests that the TGAI (Refined Oil of *Nepeta cataria*) is non-mutagenic. As such, no further genotoxicity testing is required, and the requirement for higher Tier studies (ie Oncogenicity, OPPTS 870.4200) is not triggered.

cc: Roger Gardner, Kent R. Carlson, Raderrio Wilkins, Clara Fuentes, BPPD Chron File, IHAD/ARS

Kent R. Carlson, FT, PY-S: 08/12/08

Linda Hollis/DC/USEPA/US

05/28/2008 09:09 PM

To "Thomas C McEntee"  
<Thomas.C.McEntee@usa.dupont.com>, Pv  
Shah/DC/USEPA/US@EPA, Karen  
cc Raderrio Wilkins/DC/USEPA/US@EPA

bcc

Subject Re: e-courtesy copy -- formal request to add inert

It has been noted that this is a courtesy copy. The Agency will act on an official copy submitted to the document processing center per my last email to you. Once submitted, the -nerts branch will determine if the information is sufficient to review.

to -----Sent by EPA Wireless E-Mail Services.

----- Original Message -----

From: Thomas C McEntee [Thomas.C.McEntee@usa.dupont.com]

Sent: 05/28/2008 04:45 PM AST

To: Pv Shah; Karen Angulo

Cc: Linda Hollis; Raderrio Wilkins

Subject: e-courtesy copy -- formal request to add inert

Dr. PV Shah and Ms. Karen Angulo,

The attached file was expressed to IIAB today.

If you have any questions, please feel free to call or e-mail.

(See attached file: [REDACTED])

Tom McEntee  
302 695 6856  
978 335 8055 CELL

Hollis.Linda@epamail.epa.gov

05/28/2008 01:31 PM

To  
Thomas C McEntee/AE/DuPont@DuPont  
cc  
Wilkins.Raderrio@epamail.epa.gov,  
Shah.Pv@epamail.epa.gov,  
andersen.janet@epa.gov

Subject  
Re: Resubmission of Information  
71654 - ER and EG

\*Inert ingredient information may be entitled to confidential treatment\*

Dear Mr. McEntee:

Your application remains to be deficient and we can not proceed with review of the applications for the end use formulations with the inert clearance issue being unresolved. We renegotiated the PRIA due date for your product to reflect a date of November 2008 with the understanding that in doing so, the materials necessary for the Inerts Branch to review and possibly resolve the inerts issue were in house and were in the queue. I have learned as of yesterday in a conversation with both Karen Angulo and Prakashcha Shah (Pv Shah) of the Inerts Branch that you have not submitted a formal request or petition to have the inert reviewed for clearance. You indicated in an email to Karen Angulo information that you intended to present at the presubmission meeting scheduled for April 23, 2008. Unfortunately, you did not show up for the meeting and the Inerts Branch has to date not received any formal submission from you. It is also unclear from your email to Karen Angulo whether or not your interest lies in clearance for a food or non food use. At any rate, the email to K. Angulo, does not suffice or negate the need for you to make a formal submission. The information submitted in the email, per the Inerts group is not sufficient for them to consider, further, your request, per the Inerts Group is not currently on their schedule. In order for the Inerts Group to review your request, they will need an official/formal request/petition. The Inerts group will not add you to their schedule until your and successfully completed the following steps:

- 1) submit a formal submission (non-food) and or petition (food) to IIAB, and;
- 2) It is determined by the Inerts Group that it is sufficient to work on. When this determination is made, the Inerts group may be able to give you an estimated completion timeframe.

This missing information will affect your new due date as the time frame was calculated based on the understanding that your information had been officially submitted and was being reviewed. As a result, you will only have 75 days from the date of this email (August 11, 2008) to officially submit the above information through the EPA Document Processing Center. Failure to submit the information by August 11, 2008 will result in a can not grant for the end use applications.

Linda A. Hollis  
Chief, Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs (7511P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202  
hollis.linda@epa.gov  
(703) 308-8733 (phone)  
(703) 308-7026 (fax)  
Visit <http://www.epa.gov/pesticides>

Thomas C McEntee

<Thomas.C.McEnte  
e@usa.dupont.com  
>

05/28/2008 10:55  
AM

To  
Linda Hollis/DC/USEPA/US@EPA,  
Raderrio Wilkins/DC/USEPA/US@EPA  
cc

Subject  
Re: Resubmission of Information  
71654 - ER and EG

(See attached file: 20080528 Resend cover letter inert Lotion  
substitutue.pdf)

Mr. Raderrio Wilkins,

Refer to the cover letter from May 8, 2008 and the added page from EPA  
DER  
9/19/07. Following the November 20067 meeting with you, the formulas  
were  
revised to substitute chemically and functionally equivelant ingredients  
which are on EPA's list with the exception of one inert. This inert is  
the  
subject of the submission to IIRB on April 30, 2008.

Tom McEntee  
302 695 6856  
978 335 8055 CELL

Hollis.Linda@epam  
ail.epa.gov

To  
05/13/2008 11:53  
McEntee/AE/DuPont@DuPont,  
AM

Thomas C  
Wilkins.Raderrio@epamail.epa.gov

cc

Subject

Re: Resubmission of Information  
71654-EN, ER, EG and EL

I believe that your submission was submitted late in addition to the fact that there were deficiencies outlined in our letter which you have not addresses in your resubmission. I am unclear as to your involvement with the inerts group for clearance however the information as resubmitted thus far remain deficient. You may either renegotiate or we will elect to issue a can not grant. Alternatively, you can withdraw.

-----Original Message-----

From: Thomas C McEntee

To: Raderrio Wilkins

To: Linda Hollis

Sent: May 13, 2008 11:06 AM

Subject: Fw: Resubmission of Information 71654-EN, ER, EG and EL

Mr. Raderrio Wilkins,

Thank you for your telephone call. I am still trying to confirm that IIRB

has received the documents on the unlisted inert from our supplier, which

affect the review cycle for the end-use formulated lotions.

Returning to the previous negotiated date for the Nepeta

catariaTechnical

and Manufcaturing Use Product (71654- EN) [EPA letter of Nov. 8, 2007], the

PRIA date was May 30, 2008. We met the target date of February 2008 for

re-submission. Extension of the PRIA date out to November for the technical registration does not seem justified.

Please let me know of any developments which are a basis for your suggestion of a November date for the technical registration.

Thank you for your attention to our applications.

Tom McEntee

302 695 6856

978 335 8055 CELL

----- Forwarded by Thomas C McEntee/AE/DuPont on 05/13/2008 10:44 AM

-----

Thomas C

McEntee/AE/DuPont

To

05/06/2008 05:54

Hollis.Linda@epamail.epa.gov@DUPONT

PM

\_MHUB

cc

wilkins.raderrio@epa.gov

Subject

Re: Fw: Resubmission of

Information 71654-EN, ER, EG and EL

(Document link: Thomas C McEntee)

Ms. Linda Hollis,

Thank you for your e-mails. I will be completing the submissions on the end-use formulas this week.

This is to confirm that I will request a renegotiated action date for the applications in the subject family, based on the complexity and date of last submission.

"Refined Oil of Nepeta cataria Technical and Manufacturing Use Product"  
EPA

File Symbol 71654-EN

"Refined Oil of Nepeta cataria" 15% Lotion; EPA File Symbol 71654-ER

"Refined Oil of Nepeta cataria" 7% Lotion; EPA File Symbol 71654-EG

"Refined Oil of Nepeta cataria" 7% Liquid; EPA File Symbol 71654-EU

"Refined Oil of Nepeta cataria" 15% Liquid; EPA File Symbol 71654-EL

Reference: EPA letter of October 17, 2007

EPA letter of August 29, 2007

EPA letter of April 16, 2008

EPA-Dupont November 8, 2007 meeting

(See attached file: [REDACTED])

-----Original Message Truncated-----

to -----\Sent by EPA Wireless E-Mail Services.

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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

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(See attached file: 20080528 Resend cover letter inert Lotion substitue.pdf) [attachment "20080528 Resend cover letter inert Lotion substitue.pdf" deleted by Thomas C McEntee/AE/DuPont]

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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

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# Registration Details

Company: 71654 E.I. DUPONT DE NEMOURS AND COMPANY

Risk Mgr: RM 91 Biologicals & Pollution Prevention Division, PM Team 91

Organization: BPPD / EPS

Current Status: Under Review (02-Nov-2006)

Reg. Number: 71654-EN

Pesticide Type: Biochemical

High Exposure: ☐

Use Type: MP

Signal Word: Caution

Repack: ☐ Yes ☒ No

Latest Approved Label:

NPIC Phone: ☐ Yes ☒ No

No Ingredient? ☐

WPS Written Notification: ☐ Yes ☒ No

Related Products

Restricted Use

Reg. Expiration Date

Use Patterns

Transfer History

Toxicology

Mode Of Action

FR Notice

Receipts

Product Name

Ingredient

Formulation Property

Pesticide Category

Permitted State

Product Name

Name Status

REFINED OIL OF NEPETA CATARIA

Active

71654-EN ✓  
ER ✓  
EU ✓  
EG ✓  
EL ✓

MAY 23 2008

5/ SUBMISSIONS  
included!  
HERE!

WPS-PPE

Label Image

Container Info

Tracking

Status

Sites/Pests

CSF

Data Requirements

Generate Rqmts

Inert Ingredients

art


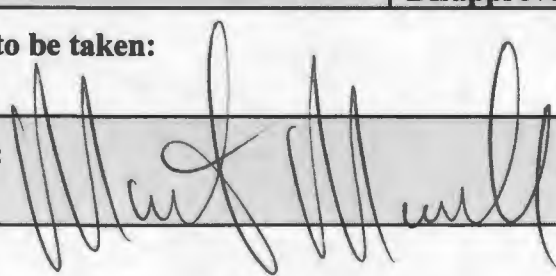
Welcome - Lotus

EPA-PRISM Main - ...

2:52 PM

Roderrio

**Recommendation of Division Directors  
Negotiated Due Dates**

<b>Decision#:</b> 371861	<b>Registration#:</b> 71654-EN	<b>Petition #:</b> N/A
<b>Fee Category:</b> B60 (PRIA 1)		<b>PRIA Decision Time Frame:</b> 12 months
<b>Submitted by:</b> Raderrio Wilkins	<b>Branch:</b> BPB	<b>Date:</b> May 19, 2008
<b>Company:</b> Dupont Chemical Solution		
<b>Original Due Date:</b> Nov. 17, 2007	<b>Proposed New Due Date:</b> November 30, 2008	
<b>Previous Negotiated Due Dates:</b> 5/30/08		
<b>Is the "Fix" in-house?</b> No		<b>If not, date "Fix" expected:</b> 6/13/08
<b>Issue (describe in detail):</b> In BPPD's agreement of November 8, 2007, Dupont Chemicals were to submit the following deficient data (refer to deficiency letter dated 10/16/07): Product Chemistry (CSF deficiencies), Change in four inerts (submit inerts substantially similar), Efficacy (submit information regarding description of studies, species etc.), and Mutagenicity Study (Point Mutag. Assay to validate or confirm results) for products 71654-EN, -ER, -EG, -EU and -EL by the end February 2008 to support the bridging of data. The Agency received the resubmitted data package in mid-March. Furthermore, the product contain four inerts in the formulation that are not cleared for use which the registrant did not address in their resubmission as outlined in the Agency's letter of October 16, 2007. Failure to submit the missing data by the end of February impacted the new Pria Date of May 30, 2008. To date, the information as resubmitted remains incomplete.		
<b>Summary of Deficiency Type(s):</b> <b>Not Submitted (N)</b> <b>Deficiencies (D)</b> <b>Product Chemistry:</b> <u>  D  </u> <b>Acute Tox:</b> <u>  D  </u> <b>Efficacy:</b> <u>  D  </u> <b>Labeling:</b> <u>      </u> <b>Other (describe):</b> <u>      </u>		
<b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b> The company's agent (Mr. Thomas McEntee) is extremely uncooperative and slow in responding to Agency letters, emails and telephone messages initiated by the Regulatory Manager and Branch Chief.		
<b>"75 Day" Letter sent?</b> <u>  10/16/07  </u> (Date sent) <b>Yes</b> <u>      </u> <b>No and reason for none?</b>		
<b>Note:</b> Application was submitted under PRIA 1		
<b>Rationale for Proposed Due Date:</b> The resubmitted information would require BPPD Phase review of Phases II – V, which is equivalent to 6 months. The 180 day extension would allow the registrant time to resolve their formulation problem by change the four inert to a substantially similar chemical or submit an application for inert clearance to RD.		
<b>Registrant notified that this is the last negotiation?</b> <u>  X  </u> <b>Yes</b> <u>      </u> <b>submission was submitted and</b> <u>      </u> <b>Not Applicable</b>		
<b>Approve:</b> 	<b>Disapprove:</b>	
<b>If disapproved, action to be taken:</b>		
<b>OD or DOD Signature:</b> 	<b>Date:</b> 5-29-08	



DuPont Chemical Solutions Enterprise

May 14, 2008

Ms. Linda Hollis  
Biopesticides and Pollution Prevention Division (BPPD)  
US Environmental Protection Agency  
Office of Pesticide Programs (7504P)  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

Subject: Renegotiated PRIA Due Dates

"Refined Oil of *Nepeta cataria* Technical; EPA File Symbol 71654-EN  
"Refined Oil of *Nepeta cataria*" 15% Lotion; EPA File Symbol 71654-ER  
"Refined Oil of *Nepeta cataria*" 7% Lotion; EPA File Symbol 71654-EG  
"Refined Oil of *Nepeta cataria*" 7% Liquid; EPA File Symbol 71654-EU  
"Refined Oil of *Nepeta cataria*" 15% Liquid; EPA File Symbol 71654-EL

Reference: EPA letter of October 17, 2007  
EPA letter of August 29, 2007  
EPA letter of April 16, 2008  
EPA-Dupont November 8, 2007 meeting

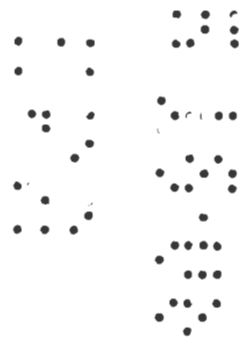
DuPont is accepting a renegotiated PRIA due date of November 30, 2008 which allows six months for EPA review of all of the items.

Should there be any questions, please feel free to call.

Thank you for your assistance with our applications.

Sincerely,

  
Thomas C. McEntee  
Product Registration Manager  
[Thomas.C.McEntee@usa.dupont.com](mailto:Thomas.C.McEntee@usa.dupont.com)  
(302) 695 6856



APR 16 2008

DuPont Chemical Solutions Enterprise  
 c/o Thomas C. McEntee  
 P.O. Box 80402  
 Wilmington, DE 1988-0402

Re: Application for a Biopesticide Registration  
 Refine Oil of Nepeta cataria  
 EPA File Symbol: 71654-ER, EG, EN, EL and EU

Dear Mr. McEntee:

Please refer to my email dated March 13, 2008. It should be noted that there were 86-5 deficiencies that you have responded to and at this time do not know if the data are 86-5 compliant. This delay in submission prompted our need to renegotiate the due date for all of the above products because too much time has now lapsed for EPA to review any materials in support of the above submissions and make a regulatory decision by the due dates of May 30th and June 30th respectively. Our recommendation initially was for you to renegotiate the due dates for all of the above products to be in line with the due date of your -EU product of August 30, 2008.

Mr. Wilkins has informed me that there are additional outstanding issues which have not been addressed in this most recent resubmission. Our letter to you dated October 16, 2007 which referenced pending products: 71654- EG and ER, EL and EU, stated that your formulations contained inert ingredients that were not cleared. Our policy is such that any inert ingredient contained in a formulation must be cleared prior to the issuance of registration. Under PRIA 2, inert clearance for the Biopesticides and Pollution Prevention is not considered a PRIA action. You may submit the information in support of inert clearance to the Agency in a separate application. The Registration Division is responsible for clearing all inert ingredients. BPPD will however, consult with the Registration Division on inerts subject to be used in formulation for BPPD products. Nonetheless, this is a function that must be done before your application can even be considered for regulatory review. Therefore, you will need to make some decisions. While there is no statutory timeframe attached to clearance of inert ingredients, I understand that the process can be at the minimum six months, but this will depend on the workload of those involved. You have made reference to working with Kerry Leifer of the Agency. While Mr. Leifer does work in the branch responsible for clearance of inerts, you must make an application to the Agency to do so.

SYMBOL	▶	We will therefore need to know, with some urgency how you will proceed. You have the					
SURNAME	▶	following options:					
DATE	▶	4/16/08					

(A). Renegotiate the due date for all of the above actions and consider the time that it will take for you to make a separate application to the Agency for inert clearance and have the Agency to conduct review. It is important to note that you can negotiate the due date for a time frame that you feel is feasible, regardless of the length.

(B). Withdraw the applications until such time when you have addressed the deficiencies and have all of the data to submit.

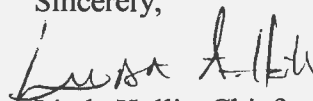
(C). Reformulate the product so that all inert ingredients have been cleared. Should you elect this method, you will run the risk of having to withdraw the pending products given that we have already conducted primary reviews and the fact that the formulations may not be substantially similar.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for the action category (B60) of twelve months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, there may not be enough time remaining before the PRIA decision date of May 30, 2008 for you to submit the information requested above and for BPPD to complete the review and make a regulatory decision. While these are the major deficiencies that are associated with your application, BPPD is still reviewing other portions of your package.

Therefore, you may renegotiate the due dates for the five products above, or withdraw the application and resubmit when you have all the information or the Agency will issue a can not grant letter under PRIA on or about May 30, 2008. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product immediately from the date of this letter at (703) 308-1259 with your response.

Sincerely,



Linda Hollis, Chief  
Biochemical Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)

## Memorandum

Date: 3 / 17 / 08

To: BPPD (91), Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission  
☐ partially accepted submission  
☐ rejected submission

# Receipt for Section 3

S: 825993

Resubmission: ☒ Yes ☐ No

Regulatory Type: Product Registration - Section 3

Fast Track Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 71654 E.I. DUPONT DE NEMOURS AND COMPANY ☒

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 71654-EN Product Name: REFINED OIL OF NEPETA CATARIA

Overnight: ☐

Me Too Section3: ☐ Me Too Product Name:

Application Date: 13-Mar-2008 ☒

OPP Rec'd Date: 13-Mar-2008 ☒

Front End Date: 13-Mar-2008 ☒

Risk Manager Send Date: 13-Mar-2008 ☒

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

resubmission following 86-5 rejection

New Ingredient Request Date:

New Ingredient Replied Date:

Signature Date:

Form A: ☐ Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

Resubmission  
Please forward to  
Raderio.  
MAR 18 2008 *Thir*

AIO - Raderio  
MAR 18 2008  
*sdh*



Linda Hollis/DC/USEPA/US  
03/13/2008 11:51 AM

To Thomas C McEntee  
<Thomas.C.McEntee@usa.dupont.com>  
cc Driss Benmhend/DC/USEPA/US@EPA, Raderrio  
Wilkins/DC/USEPA/US@EPA  
bcc  
Subject Resubmission of Information 71654-EN, ER, EG and EL

Dear Mr. McEntee:

I understand that you have been in conversation with Raderrio Wilkins of my staff regarding the fact that data that was to be submitted (in agreement between Dupont and the Agency) by the end of February to address deficiencies in the above product has only arrived within the past week. It should be noted that there were 86-5 deficiencies that you have responded to and at this time do not know if the data are 86-5 compliant. This delay in submission prompted our need to renegotiate the due date for all of the above products because too much time has now lapsed for EPA to review any materials in support of the above submissions and make a regulatory decision by the due dates of May 30th and June 30th respectively. Our recommendation initially was for you to renegotiate the due dates for all of the above products to be in line with the due date of your -EU product of August 30, 2008.

Mr. Wilkins has informed me that there are additional outstanding issues which have not been addressed in this most recent resubmission. Our letter to you dated October 16, 2007 which referenced pending products: 71654- EG and ER, EL and EU, stated that your formulations contained inert ingredients that were uncleared. Our policy is such that any inert ingredient contained in a formulation must be cleared prior to the issuance of registration. Under PRIA 2, inert clearance for the Biopesticides and Pollution Prevention is not considered a pria action. You may submit the information in support of inert clearance to the Agency in a separate application. The Registration Division is responsible for clearing all inert ingredients. BPPD will however, consult with the Registration Division on inerts subject to be used in formulation for BPPD products. Nonetheless, this is a function that must be done before your application can even be considered for regulatory review. Therefore, you will need to make some decisions. While there is no statutory timeframe attached to clearance of inert ingredients, I understand that the process can be at the minimum six months, but this will depend on the workload of those involved. You have made reference to working with Kerry Leifer of the Agency. While Mr. Leifer does work in the branch responsible for clearance of inerts, you must make an application to the Agency to do so.

We will therefore need to know, with some urgency how you will proceed. You have the following options.

- A. Renegotiate the due date for all of the above actions and consider the time that it will take for you to make a separate application to the Agency for inert clearance and have the Agency to conduct review. It is important to note that you can negotiate the due date for a time frame that you feel is feasible, regardless of the length.
- B. Withdraw the applications until such time when you have addressed the deficiencies and have all of the data to submit.
- C. Reformulate the product so that all inert ingredients have been cleared. Should you elect this method, you will run the risk of having to withdraw the pending products given that we have already conducted primary reviews and the fact that the formulations may not be substantially similar.

Please respond to Mr. Wilkins in a timely fashion.

Linda A. Hollis  
Chief, Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division

Office of Pesticide Programs (7511P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202  
hollis.linda@epa.gov  
(703) 308-8733 (phone)  
(703) 308-7026 (fax)  
Visit <http://www.epa.gov/pesticides>



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

March 13, 2008


OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

E.I. DUPONT DE NEMOURS AND COMPANY  
DUPONT CHEMICAL SOLUTIONS ENTERPRISE  
PO Box 80402  
WILMINGTON, DE 19880-0402

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 13-MAR-08. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

 Driss  
Benmhend/DC/USEPA/US  
03/12/2008 09:04 AM

To thomas.c.mcentee@usa.dupont.com  
cc Raderrio Wilkins/DC/USEPA/US@EPA, Linda  
Hollis/DC/USEPA/US@EPA  
bcc  
Subject Resubmission 86-5 Failure

Dear Mr. McEntee:

The attached file is in reference to the above registration. Please call me if you have any questions or a problem with the pdf. file.

Thank you,



Dupont.86.5.pdf DuPont.86.5 Failure.doc

-----

-----

*Driss Benmhend*

Biopesticides and Pollution Prevention Division (7511P)

Office of Pesticide Programs

The United States Environmental Protection Agency

1200 Pennsylvania Avenue. N.W.

Washington, DC 20460

(703) 308-9525

Benmhend.driss@epa.gov

[www.epa.gov/oppbppd1/biopesticides/](http://www.epa.gov/oppbppd1/biopesticides/)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

March 11, 2008

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

E.I. DUPONT DE NEMOURS AND COMPANY  
PO Box 80402  
WILMINGTON, DE 19880-0402

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 04-MAR-08. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.


The rejected studies and their deficiencies are described below.

Rejected Study [01]:

\* FIFRA Section 10(d)(1) only provides for confidentiality of information which: (A) discloses manufacturing or quality control processes, (B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or (C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide... Since your claim covers information entirely outside this narrow range of subject matter, it cannot be accepted.

for the reasons

Raderrio  
Wilkins/DC/USEPA/US  
03/11/2008 03:24 PM

To Thomas C McEntee  
<Thomas.C.McEntee@usa.dupont.com>  
cc Linda Hollis/DC/USEPA/US@EPA, Driss  
Benmhend/DC/USEPA/US@EPA  
bcc  
Subject Refine Oil of Nepeta cataria EPA File Symbol  
71654-ER,EG,EN, EL, and EU - Ref: Nov. 8, 2007 Meeting  


Dear Mr. McEntee,

Per the Agency's email of February 21, 2008, informing Dupont Chemicals that you were to submit the following deficient data (refer to deficiency letter dated 10/16/07): Product Chemistry (CSF deficiencies), Change in four inerts (submit inerts substantially similar), Efficacy (submit information regarding description of studies, spices etc.), and Mutagenicity Study (Point mutag. Assay to validate or confirm results ) for products 71654-EN, ER, EG and EL by the end February 2008. On February 25, 2008, BPPD received a response to our e-mail notifying the Agency that the requested data would be Fed Ex'ed on Thursday 28, 2008. To date, the Agency is not in receipt of your data package.

As previously mentioned, failure to submit the missing data by the end of February 2008 would impact the new Pria Dates of May 30, 2008 and June 30, 2008 (the renegotiated PRIA Due Date was contingent on the resubmission of 2/08). Should the data referenced above be received after the agreed date of February 2008, you were informed that an additional renegotiation will be necessary. Unfortunately there is not enough time remaining before the PRIA decision date of May 30, 2008 and June 30, 2008 for you to submit the information requested above and for BPPD to complete the review and make a regulatory decision..

Therefore, you may renegotiate the due date, or withdraw the application and resubmit when you have all the information or the Agency will issue a can not grant letter under PRIA on or about May 30, 2008. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product immediately at (703) 308-1259 with your response.

Sincerely,  
Raderrio Wilkins

Thomas C McEntee <Thomas.C.McEntee@usa.dupont.com>



Thomas C McEntee



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

March 11, 2008

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

E.I. DUPONT DE NEMOURS AND COMPANY  
PO Box 80402  
WILMINGTON, DE 19880-0402

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 04-MAR-08. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.

The rejected studies and their deficiencies are described below.

Rejected Study [01]:

\* FIFRA Section 10(d)(1) only provides for confidentiality of information which: (A) discloses manufacturing or quality control processes, (B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or (C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide... Since your claim covers information entirely outside this narrow range of subject matter, it cannot be accepted.

## Memorandum

Date: 3 / 11 / 08

To: BPPN (91), Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☐ fully accepted submission  
☒ partially accepted submission  
☐ rejected submission

86-5 letters  
sent on 3/12/08  
DJ

Receipt for Section 3

S: 825686

Regulatory Type: Product Registration - Section 3

Application Type: Miscellaneous Receipt

Company: 71654 E.I. DUPONT DE NEMOURS AND COMPANY

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 01

Product #: 71654-EN Product Name: REFINED OIL OF NEPETA CATARIA

Me Too Section3: Me Too Product Name:

Application Date: 28-Feb-2008 OPP Rec'd Date: 04-Mar-2008

Front End Date: 05-Mar-2008 Risk Manager Send Date: 05-Mar-2008

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: New Ingredient:

Receipt Description: response to letter of 10/17/07

Form A: Signature Date: Form B: Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

Failed  
86-5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Thomas C. McEntee  
Product Registration manager  
DuPont Chemical Solutions Enterprise  
P. O. Box 80402  
Wilmington, DE 19880-0402

RE: **Refined Oil of *Nepeta cataria* Technical and Manufacturing Use Product**  
**EPA File Symbol: 71654-EN, ER, EG**  
**Application dated: 02/28/08**  
**Notification of Non-compliance with Pesticide Registration Notice 86-5**

Email sent date: 03/12/08  
Email address: Thomas.c.McEntee@usa.dupont.com

Dear Mr. McEntee:

The Biopesticides and Pollution Prevention Division (BPPD) have received your submission to register the subject product. All or some of the data were rejected by our Document Processing Unit because they were not submitted as directed in PR Notice 86-5 and should be reformatted and resubmitted to the Document Processing Unit. A copy of PR Notice 86-5 can be found at our website at: [http://www.epa.gov/opppmsd1/PR\\_Notices/pr86-5.html](http://www.epa.gov/opppmsd1/PR_Notices/pr86-5.html) should you need assistance in making the necessary changes.

If you still want to register this product, the application will be kept open for a period of 75 days to give you an opportunity to respond to this memorandum. If you find that you need more time you must request an extension for a reasonable stated period of time. Extension requests must be made immediately to me at (703) 308-8713.

If you do not comply with this procedure by not responding to this letter or requesting an extension of time to resubmit the information, the Agency may administratively withdraw your application from further consideration under the provisions of PR Notice 75-4 of August 27, 1975. Once this is done, you will have to submit completely new application should you wish to pursue the registration of your product after the application has been withdrawn.

The changes and/or corrections required by you are outlined in the attached EPA Transmittal Letter. You must contact me by telephone at the number above or by email at [benmhend.dirss@epa.gov](mailto:benmhend.dirss@epa.gov) and indicate that you will submit the corrected pages via facsimile to **(703) 305-0118**. Once you have faxed the corrected pages, please follow up with an email to me indicating that you have done so.

If the changes are excessive, you may wish to fed-ex or courier the documents to our offices or contact me to arrange to come in to our offices to make the necessary changes. Once all changes have been made, your submission will be forwarded to our Document Processing Unit for PR Notice 86-5 Screening.

Should you have additional questions regarding this matter, please feel free to contact Driss Benmhend, Acting Team Leader for Biochemical Pesticides Branch at (703) 308-9525 or by email [benmhend.driss@epa.gov](mailto:benmhend.driss@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Driss Benmhend", with a stylized, flowing script.

Driss Benmhend  
Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention  
Division (7511P)

Enclosure



DuPont Chemical Solutions Enterprise

February 28, 2008

Mr Raderrio Wilkins  
Biopesticides and Pollution Prevention Division (BPPD)  
US Environmental Protection Agency  
Office of Pesticide Programs (7504P)  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

Subject: Resubmission -- New Pesticide Application for Registration  
"Refined Oil of *Nepeta cataria* Technical and Manufacturing Use Product"  
EPA File Symbol : 71654-EN

This letter and its attachments comprise DuPont's response to your letter of October 17, 2007 as discussed in our November 8, 2007 meeting.

#### I. CSF

The attached Confidential Statement of Formula (EPA form 8570-4) dated February 25, 2008 and the companion check sheet answer comments "a." through "k." of your letter.

#### III. PHYSICAL PROPERTIES

The attached volume, **Supplement to Preliminary Analysis, Physical and Chemical Characteristics** addresses comments **III. a through d.**

Your letter does not have a paragraph headed "Toxicology" or Human Safety, but on page 2, "2" states that "Tier 1 Toxicity Studies are **ACCEPTABLE**." During our November 8, 2007 meeting there was discussion concerning mutagenicity results and a suggestion that further testing is a consideration. DuPont did not have a mutagenicity expert at the meeting and telephone attempts were made to engage a toxicologist during the meeting without success.

Subsequent to the meeting, expert opinion has been obtained which is included in the attached report, **Response from DuPont to the U.S. EPA Genetic Toxicity Recommendation in "Science Review and Human Health Risk Assessment in Support of the Registration of the Insect Repellent Refined Oil of *Nepeta cataria* (TGAI), and two lotion end-use products."**

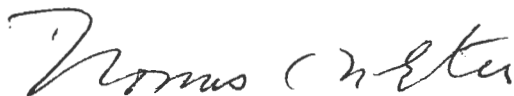
#### IV. PRODUCT PERFORMANCE

Comments "a". through "d" are addressed in the attached report, **Supplement to "Evaluation of the efficacy of personal repellents against mosquitoes in Maine" (MRID 46977424), "Evaluation of the efficacy of personal repellents against mosquitoes in Florida" (MRID 46977425) and "Evaluation of the efficacy of personal repellents against blackflies in Maine".**

Should there be any questions, please feel free to call.

Thank you for your assistance with our applications.

Sincerely,



Thomas C. McEntee

Product Registration Manager

**Thomas.C.McEntee@usa.dupont.com**

(302) 695 6856

TRANSMITTAL DOCUMENT

**Attention:**

Document Processing Desk (RESUB)  
Mr. Raderrio Wilkins  
Biopesticides and Pollution Prevention Division (BPPD)  
US Environmental Protection Agency  
Office of Pesticide Programs (7504P)  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

**NAME AND ADDRESS OF SUBMITTER**

E.I. du Pont de Nemours and Company  
DuPont Chemical Solutions Enterprise  
Experimental Station (ESL 402/3442A)  
P. O. Box 80402  
Wilmington, DE 19880-0402

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-

**Resubmission --- Application for New Pesticide Registration End-Use Product**

**Refined oil of *Nepeta cataria* Technical and Manufacturing Use Product; EPA File Symbol 71654-EN**

Transmittal Date: **February 28, 2008**

**Transmittal Material:**

Volume 1     Administrative Materials

- Cover Letter	1 page
- Transmittal Document	1 pages
- CSF (EPA Form 8570-4), February 25, 2008	1 page

Volume 2A     Chemistry

**47370401     Supplement to Preliminary Analysis, Physical and Chemical Characteristics** <sup>5</sup> **7** pages  
McEntee, Thomas C., E.I. duPont de Nemours and Company, February 25, 2008.

**47362602     Volume 2B     Chemistry (Cont.)**

**SUPPLEMENT: PREDICTION OF MINOR CONSTITUENTS OF  
REFINED OIL OF *Nepeta cataria* AS LIKELY HYDROGENATION  
PRODUCTS;** Scialdone, Mark A. and Hallahan, David L.; E.I. duPont de  
Nemours and Company, February 21, 2008. 47 pages

Volume 3

- 47362603** Supplement to "Evaluation of the efficacy of personal repellents against mosquitoes in Maine" (MRID 46977424), "Evaluation of the efficacy of personal repellents against mosquitoes in Florida" (MRID 46977425) and "Evaluation of the efficacy of personal repellents against blackflies in Maine" (MRID 47015602); Hallahan, David L. and Spero, Niketas C. E. I. duPont de Nemours and Company and ICR Inc., February 1, 2008. 20 pages

Volume 4

- 47362604** Response from DuPont to the U.S. EPA Genetic Toxicity Recommendation in "Science Review and Human Health Risk Assessment in Support of the Registration of the Insect Repellent Refined Oil of *Nepeta cataria* (TGAI), and two lotion end-use products.", McEntee, Thomas C. (editor) E.I. duPont de Nemours and Company, February 25, 2008. 5 pages



<Thomas.C.McEntee@usa.d  
upont.com>

02/25/2008 09:57 AM

To Raderrio Wilkins/DC/USEPA/US@EPA

cc

Subject Re: Refine Oil of Nepeta cataria - Ref: Nov. 8, 2007 Meeting

Mr. Raderio Wilkins,

I expect to Fed Ex the data on Thursday Feb. 28 for arrival Friday Feb. 29th.

Thank you for your attention to our applications.

Tom McEntee  
302 695 6856  
978 335 8055 CELL

Wilkins.Raderrio@  
epamail.epa.gov

02/21/2008 09:58  
AM

Thomas C McEntee/AE/DuPont@DuPont

To

cc

Hollis.Linda@epamail.epa.gov,  
Benmhend.Driss@epamail.epa.gov,  
Gardner.Roger@epamail.epa.gov,  
Carlson.Kent@epamail.epa.gov,  
Fuentes.Clara@epamail.epa.gov,  
Wilkins.Raderrio@epamail.epa.gov

Subject

Refine Oil of Nepeta cataria - Ref:  
Nov. 8, 2007 Meeting

Dear Mr. McEntee,

Per our agreement of November 8, 2007, you were to submit the following deficient data (refer to deficiency letter dated 10/16/07): Product Chemistry (CSF deficiencies), Change in four inerts (submit inerts substantially similar), Efficacy (submit information regarding description of studies, spices etc.), and Mutagenicity Study (Point mutag. Assay to validate or confirm results ) for products 71654-EN, ER and EG by the end February 2008. To date, the Agency is not in receipt of this data. Failure to submit the missing data by the end of February will impact the new Pria Date of May 30, 2008. Should the data referenced above be submitted after the agreed date of February 2008, an additional renegotiation will be necessary. In addition, the FR announcing receipt of this new active ingredient is scheduled to be published March 2008.

Sincerely,  
Raderrio Wilkins  
(703) 308-1259

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Thomas C McEntee  
<Thomas.C.McEntee@usa.d  
upont.com>

02/25/2008 09:57 AM

To Raderrio Wilkins/DC/USEPA/US@EPA

cc

bcc

Subject Re: Refine Oil of Nepeta cataria - Ref: Nov. 8, 2007 Meeting

History:

✉ This message has been forwarded.

Mr. Raderrio Wilkins,

I expect to Fed Ex the data on Thursday Feb. 28 for arrival Friday Feb. 29th.

Thank you for your attention to our applications.

Tom McEntee  
302 695 6856  
978 335 8055 CELL

Wilkins.Raderrio@  
epamail.epa.gov

02/21/2008 09:58  
AM

To  
Thomas C McEntee/AE/DuPont@DuPont  
cc

Hollis.Linda@epamail.epa.gov,  
Benmhend.Driss@epamail.epa.gov,  
Gardner.Roger@epamail.epa.gov,  
Carlson.Kent@epamail.epa.gov,  
Fuentes.Clara@epamail.epa.gov,  
Wilkins.Raderrio@epamail.epa.gov  
Subject  
Refine Oil of Nepeta cataria - Ref:  
Nov. 8, 2007 Meeting

Dear Mr. McEntee,

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announcing receipt of this new active ingredient is scheduled to be published March 2008.


Sincerely,  
Raderrio Wilkins  
(703) 308-1259

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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

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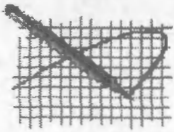
Raderrio  
Wilkins/DC/USEPA/US  
02/21/2008 09:58 AM

To Thomas C McEntee  
<Thomas.C.McEntee@usa.dupont.com>  
cc Linda Hollis/DC/USEPA/US@EPA, Driss  
Benmhend/DC/USEPA/US@EPA, Roger  
Gardner/DC/USEPA/US@EPA, Kent  
bcc  
Subject Refine Oil of Nepeta cataria - Ref: Nov. 8, 2007 Meeting 

Dear Mr. McEntee,

Per our agreement of November 8, 2007, you were to submit the following deficient data (refer to deficiency letter dated 10/16/07): Product Chemistry (CSF deficiencies), Change in four inerts (submit inerts substantially similar), Efficacy (submit information regarding description of studies, spices etc.), and Mutagenicity Study (Point mutag. Assay to validate or confirm results ) for products 71654-EN, ER and EG by the end February 2008. To date, the Agency is not in receipt of this data. Failure to submit the missing data by the end of February will impact the new Pria Date of May 30, 2008. Should the data referenced above be submitted after the agreed date of February 2008, an additional renegotiation will be necessary. In addition, the FR announcing receipt of this new active ingredient is scheduled to be published March 2008.

Sincerely,  
Raderrio Wilkins  
(703) 308-1259



Latasha  
White/DC/USEPA/US  
01/09/2008 10:50 AM

To Raderrio Wilkins/DC/USEPA/US@EPA  
cc  
bcc  
Subject DOCKET CREATED EPA-HQ-OPP-2008-0017- Refined Oil  
of Nepeta Cataria

**Receipt for Section 3**

S: 802301      Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3      Fee For Service: ☐ Yes ☒ No

Application Type: New Registration      Billable: ☐ Yes ☒ No

Company: 71654 E.I. DUPONT DE NEMOURS AND COMPANY      V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 71654-EN      Product Name: REFINED OIL OF NEPTEA CATARIA

Override#:

Me Too Section3:       Me Too Product Name:

Application Date: 30-Nov-2006      OPP Rec'd Date: 08-Dec-2006

Front End Date: 11-Dec-2006      Risk Manager Send Date: 11-Dec-2006

FFS Due Date: 17-Nov-2007      Negotiated Due Date:

OPP Target Date:

Fast Track: ☐      New Ingredient: ☐

Receipt Description: resubmission following 86-5 rejection

New Ingredient Request Date:

New Ingredient Received Date:

**Receipt Content**

Study

Print Letter

Enter More Information

Tracking

ATLAS Pro - Microsoft...      Welcome - Lotus Notes      EPA-PRISM Main - Co...      10:07 AM

AIO - Wilkins  
MAR 16 2007  
sdh

**Receipt for Section 3**

S: 803167      Resubmission: ☒ Yes ☐ No

Regulatory Type: Product Registration - Section 3      Fee For Service: ☐ Yes ☒ No

Application Type: New Registration      Billable: ☐ Yes ☒ No

Company: 71654 E.I. DUPONT DE NEMOURS AND COMPANY      V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 71654-EN      Product Name: REFINED OIL OF NEPETEA CATARIA

Override#:

Me Too Section3:       Me Too Product Name:

Application Date: 28-Dec-2006      OPP Rec'd Date: 28-Dec-2006

Front End Date: 28-Dec-2006      Risk Manager Send Date: 28-Dec-2006

FFS Due Date: 17-Nov-2007      Negotiated Due Date:

OPP Target Date:

Fast Track: ☐      New Ingredient: ☐

Receipt Description: resubmission following 86-5 rejection

New Ingredient Request Date:

New Ingredient Received Date:

Receipt Content: Study

Print Letter

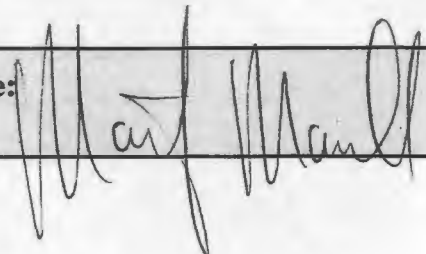
Enter More Information

Tracking

art      ATLAS Pro - Microsoft...      Welcome - Lotus Notes      EPA-PRISM Main - Co...      10:08 AM

AIO-Wilkins  
MAR 16 2007  
sdh

**Recommendation of Division Directors  
Negotiated Due Dates**

<b>Decision#:</b> 371861, 372756, and 371862		<b>Registration#:</b> 71654-EN, -EG and -ER		<b>Petition #:</b> N/A	
<b>Fee Category:</b> B60			<b>PRIA Decision Time Frame:</b> 6 months		
<b>Submitted by:</b> Raderrio Wilkins			<b>Branch:</b> BPB		<b>Date:</b> November 8, 2007
<b>Company:</b> DuPont Chemical Solution					
<b>Original Due Date:</b> November <del>21</del> <sup>17<sup>th</sup></sup> , 2007			<b>Proposed New Due Date:</b> May 30, 2008		
<b>Previous Negotiated Due Dates:</b> None (this is the company's first renegotiation)					
<b>Is the "Fix" in-house?</b> No				<b>If not, date "Fix" expected:</b> February 2008	
<b>Issue (describe in detail):</b> In a deficiency letter (dated October 16, 2007), the Agency offered DuPont Chemical Solution an opportunity to renegotiate their PRIA Due Date of November 21, 2007 to May 30, 2008 to address Product Chemistry and Performance deficiencies and submit the required Toxicology study.					
<b>Summary of Deficiency Type(s):</b> Not Submitted (N) Deficiencies (D) <b>Product Chemistry:</b> <u>D</u> <b>Acute Tox:</b> <u>D</u> <b>Efficacy:</b> <u>D</u> <b>Labeling:</b> <u>    </u> <b>Other (describe):</b> <u>    </u>					
<b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b> The company's agent (Mr. Thomas McEntee) has not responded to the 10/16/07 deficiency letter. On November 8, 2007, however, BPPD received a commitment agreement from Mr. McEntee acting on behalf of his client DuPont Chemical Solution requesting that their PRIA due date be extended to May 30, 2008.					
<b>"75 Day" Letter sent?</b> <u>October 16, 2007</u> (Date sent) Yes <u>    </u> No and reason for none?					
<b>Rationale for Proposed Due Date:</b> An extension of the PRIA decision date is equivalent to BPPD PRIA Phase IV-V, plus lag-time for generation and submission of data					
<b>Registrant notified that this is the last negotiation?</b> Yes <u>    </u> X <u>    </u> Not Applicable					
<b>Approve:</b> <u>    </u>			<b>Disapprove:</b> <u>    </u>		
<b>If disapproved, action to be taken:</b>					
<b>OD or DOD Signature:</b> 				<b>Date:</b> 11-13-07	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

November 8, 2007

Dupont Chemical Solution Enterprise  
c/o Thomas C. McEntee  
P.O. Box 80402  
Wilmington, DE 1988-0402

Re: Application for a new Biochemical Pesticide Registration for Refined Oil of *Nepeta cataria*

I Thomas McEntee agree to renegotiate the PRIA Due Dates for the following  
A: 71654-EN, EG, ER A. MAY 30, 2008  
product(s): B: 71654-EL, EU to B. JUNE 30, 2008 date.

Furthermore, I agree that this renegotiated time frame will include submission of all deficient data to be provided to the Agency AT OR AROUND Feb, 2008 date.

In addition, I understand that should the information be submitted after the agreed upon date of February 2008, an additional renegotiation maybe necessary.

Thomas C. McEntee  
(Signature of Registrant or Consultant)

Nov. 8, 2007  
(Date)

Information to be resubmitted:

- product chemistry (CSF deficiencies)
- change in 4 inerts (will submit inerts of substantial similarity)
- efficacy → supplemental info regarding description of studies, species etc to be submitted
- Mutagenicity Study to validate or confirm results of originally submitted study, (Pant Mutation Assay)

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- Refer to def. letter dtd. Oct. 16, 2007, minutes of 11-8-07 meeting & Addendum to def. Hr. dtd. 11-8-07

~~Registration Meeting~~ Nov. 8, 2007

Registration Meeting w/ DuPont Chem

<u>Name</u>	<u>Title</u>	
1. Roderio Wilkins	BPPB	Reg. Action Coord.
2. Clara Fuentes	BPPB	Sci. Reviewer
3. Roger Gardner	BPPD/BPB	Branch Senior Scientist
<del>4. Kent Carlson</del>	BPPD/BPB	SCIENTIST
5. LINDA Hollis (703-308-8733)	BPPD/BPP	Branch chief
6. DAVID HALLAHAN	DUPONT	RESEARCH ASSOC.
7. Shannon Bullard	DUPONT	Project Leader
8. Tom McEntee	DUPONT	Product registration manager

# **FEE FOR SERVICE**



Biopesticides and  
Pollution  
Prevention  
Division

**FAX**

October 22, 2007

TO: Mr. McEntee  
Dupont  
302-695-6856  
302-6951579 (fax)

FROM: Raderrio Wilkins  
US EPA Office of Pesticide Programs  
Biopesticides & Pollution Prevention Division (7511P)  
1200 Pennsylvania Ave NW, Washington, DC 20460  
703-308-1259 Fax 703-305-0118  
Wilkins.raderrio@epa.gov

RE: AMVAC AZA 1.2% ME (EPA File Symbol 5481-LGL)

MESSAGE: Please call to confirm receiving this fax. Thanks in advance for your cooperation.



Thomas C McEntee  
<Thomas.C.McEntee@usa.dupont.com>  
10/17/2007 04:08 PM

To Raderrio Wilkins/DC/USEPA/US@EPA  
cc  
bcc  
Subject Re: Refined Oil of Nepeta cataria FAX # 302 695 1579

Mr. Raderrio Wilkins,

This is to confirm that I understand that the fax machine is not confidential and that you cannot guarantee the confidentiality of any letter that is transmitted by facsimile machine.

I will stand by the machine with fax number 302 695 1579, if you will e-mail or call when you are about to transmit.

Thank you for your assistance.

Tom McEntee  
302 695 6856  
978 335 8055 CELL

Wilkins.Raderrio@  
epamail.epa.gov

10/17/2007 03:46  
PM

To  
Thomas C McEntee/AE/DuPont@DuPont  
cc  
Hollis.Linda@epamail.epa.gov  
Subject  
Re: Refined Oil of Nepeta cataria

Dear Mr. McEntee :

The reviews for 71654-EG,ER and EN (Refined Oil of Nepeta cataria) submissions have been completed. You requested have the letters faxed to you, but they contain confidential business information (CBI). Since there is CBI, the Agency cannot fax the reviews/letters without a note from you indicating that you are aware that the facsimile machine is not confidential and that the Agency cannot guarantee confidentiality if you wish that the reviews/letters are faxed to you.

If you wish to have these faxed then respond via email that you understand that the Agency cannot guaranteed confidentiality and that you still want to have the reviews/letters faxed anyway. Please also include the fax number where you will be waiting for the fax. I will email you when I am going to send the fax. The signed originals were mailed on October 16, 2007.

Furthermore, please keep in mind that any response regarding these reviews/letters must be sent to the Agency, in writing, through the "Front-End Processing Desk."

Regards,  
Raderrio Wilkins  
Regulatory Action Leader  
Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division  
USEPA

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\*Manufacturing process information may be entitled to confidential treatment\*

DuPont Chemical Solutions Enterprise  
c/o Thomas C. McEntee  
P.O. Box 80402  
Wilmington, DE 1988-0402

OCT 16 2007

Re: Application for a new Biochemical pesticide Registration  
Refined Oil of *Nepeta cataria*  
EPA File Symbol. No. 71654-EN (100%), 71654-EG (7% Lotion), 71654-ER (15% Lotion)  
Your submission of November 30, 2006 and resubmissions of December 19, 2006, December 28, 2006 and January 5, 2007.

Dear Mr. McEntee:

The applications for Biopesticide registrations referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has been reviewed by BPPD and are not acceptable at this time. The Human Health Studies, however are acceptable and satisfy the tier 1 biochemical data requirements for the TGAI and End-Use products. The Product Chemistry and Product Performance data are **not acceptable** for the following reason(s):

**I. CSF**

**EPA File Symbol 71654-EN (TGAI):**

- a. Submit s CAS Registry numbers for all ingredients on the CSF. The must be placed after the component descriptor.
- b. All impurities potentially present at >0.1% must be identified individually on the CSF (ie. [REDACTED], etc?) and have upper certified limits calculated.
- c. The information on the top row of the CSF where refined oil of *Nepeta cataria* is identified as "active technical grade" should be deleted.

d. The parentheses around the ~~amounts of~~ <sup>CONCURRENCE</sup> the remaining ingredients provided in column 13b of the CSF must be deleted.

SYMBOL	▶ 2511P						
SURNAME	▶ [Signature]						
DATE	▶ 10/11/07						

- e. The identity of the active ingredients given on the CSF and the product label must be made consistent.
- f. The certified limits are in excess of what is recommended in 40CFR 158.175(b)(2) and ranges determined in preliminary analyses. Please base the certified limits on that presented in the 40 CFR or provide justification for deviations. EPA would like to note that [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED] EPA considers this range satisfactory for regulatory purposes because the component is undetectable in the final EP products.
- g. The lower certified limits for impurities, un-reacted starting materials, etc. must be deleted.
- h. The proposed Upper certified limit for [REDACTED] should be revised to reflect the upper part of the range described in preliminary analyses [REDACTED]. EPA considers this satisfactory for regulatory purposes because the component is undetectable in the final EP products.
- i. The proposed upper certified limit for [REDACTED]  
[REDACTED]  
[REDACTED]). EPA considers these upper limits to be satisfactory, considering the variation present in source material supply, source material composition, the negligible amount of these components in EP products, [REDACTED]  
[REDACTED] and the anticipation that no additional toxicity (other than that already associated with dihydronepetalactone) will be associated with these components.
- j. Following the addition of other ingredients to the CSF, the please ensure that the percent (%) by weight totals = 100%.
- k. Please complete blocks #5. and #6. on the CSF.

**EPA File Symbol 71654-EG (7% Lotion)**

- a. Provide a complete address and CAS registry number for the component [REDACTED].
- b. Please change the CAS No. for [REDACTED] and for [REDACTED]

c. Please provide a CAS No. for the active ingredient.

d. [REDACTED]  
[REDACTED]  
[REDACTED] are not on the most recent on-line inert ingredients list (August 2004). Please provide alternate components that are on the EPA inert ingredients list or provide information to the inert ingredients branch (IIAB) for listing these (contact in IIAB - Kerry Leifer, leifer.kerry@epa.gov).

e. Please provide the chemical identities for [REDACTED]  
[REDACTED]  
[REDACTED] on the CSF.

f. Please address the discrepancy of why the content of [REDACTED]  
[REDACTED] given on the CSF does not match the content given in MRID 47003301.

g. Please address the discrepancy of why the supplier for [REDACTED]  
[REDACTED] given on the CSF does not match the supplier given in MRID 47003301.

h. Please complete blocks 5. and 6. of the CSF.

**EPA File Symbol 71654-ER (15% Lotion)**

a. The same conditions and concerns reported for the 7% lotion (above) apply for the 15% lotion.

**II. PRODUCT CHEMISTRY**

**File Symbol 71654-EG (7% Lotion)**

a. Please provide a rationale for the increase in percent weight of [REDACTED] in the 7% lotion when compared to the TGAI.

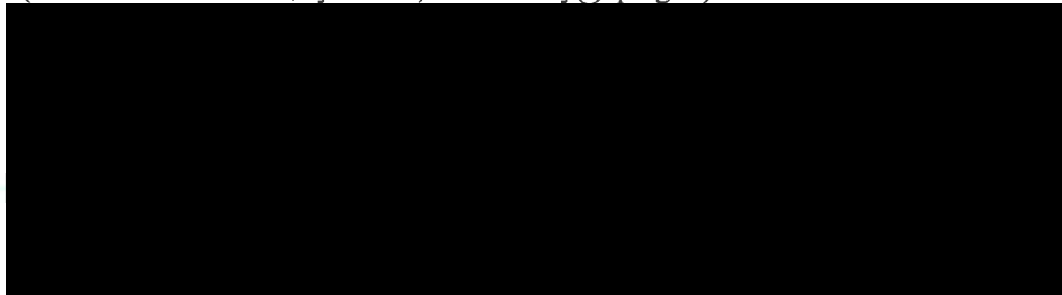
b. Submit MSDSs or specification sheets for the all beginning materials, including those present as components in the mixtures.

c. Submit quality control procedures for the formulation process.

d. Please address the observation that extended storage at ambient conditions (25°C and 60% RH) results in the degradation of dihydronepetalactone and other components.

e. Please submit information regarding the following inert ingredients (below) that are not on the most recent EPA inert ingredients list (August 2004).

BPPD recommends that the EPA inert ingredients branch (IIAB) be contacted for more information (contact in IIAB - Kerry Leifer, leifer.kerry@epa.gov).



**File Symbol 71654-ER (15% Lotion)**

- a. The same deficiencies outlined for the 7% lotion (above) apply for the 15% lotion.

**III. PHYSICAL PROPERTIES**

**EPA File Symbol 71654-EN (TGAI):**

- a. Please address explodability.
- b. Please submit storage stability and corrosion characteristics tests.
- c. Please address stability in the presence of different temperatures and metals by discussing the relative impacts that packaging and storage will have on the stability of the product.
- d. Please provide a method for the determination of density.

**File Symbol 71654-EG (7% Lotion)**

- a. Please address oxidation/reduction: chemical incompatibility and explodability.
- b. Submit storage stability and corrosion characteristics tests upon their completion.

**File Symbol 71654-ER (15% Lotion)**

- a. The same deficiencies outlined for the 7% lotion (above) apply for the 15% lotion.

2. Tier I Toxicity studies are **ACCEPTABLE**.

3. Tier I Non-Target studies have not been submitted by the registrant. EPA expects that the use pattern of this product as an insect repellent will preclude significant adverse exposure to

nontarget organisms. EPA will therefore, waive the testing guideline for Tier I non-target toxicity applicable to TGAI.

#### **IV. PRODUCT PERFORMANCE**

- a. Please provide detailed discussion on the statistics employed to analyze the data.
- b. Please address the inconsistencies concerning the amount of test material applied to subjects.
- c. It is not clear whether the landing rates for the whole body counts are based on 1 minute exposure taken for 1. This information regarding landing rates must be noted in the results table (Appendix IV).
- d. The test sites were not monitored for incidences of mosquito-borne disease prior to testing.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for the action category (B60) of twelve months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, there may not be enough time remaining before the PRIA decision date of November 21, 2007 for you to submit the information requested above and for BPPD to complete the review and make a regulatory decision. While these are the major deficiencies that are associated with your application, BPPD is still reviewing other portions of your package.

Therefore, you may renegotiate the due dates for the three products above, or withdraw the application and resubmit when you have all the information or the Agency will issue a can not grant letter under PRIA on or about November 21, 2006. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product immediately or within five (5) days from the date of this letter at (703) 308-1259 with your response.

Sincerely,



Linda Hollis., Chief  
Biochemical Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

DuPont Chemical Solutions Enterprise  
c/o Thomas C. McEntee  
P.O. Box 80402  
Wilmington, DE 1988-0402

CCT 16 2007

Re: Application for a new Biochemical pesticide Registration  
Refined Oil of *Nepeta cataria*  
EPA File Symbol. No. 71654-EN (100%), 71654-EG (7% Lotion), 71654-ER (15% Lotion)  
Your submission of November 30, 2006 and resubmissions of December 19, 2006, December 28, 2006 and January 5, 2007.

Dear Mr. McEntee:

The applications for Biopesticide registrations referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has been reviewed by BPPD and are not acceptable at this time. The Human Health Studies, however are acceptable and satisfy the tier 1 biochemical data requirements for the TGAI and End-Use products. The Product Chemistry and Product Performance data are **not acceptable** for the following reason(s):

**I. CSF**

**EPA File Symbol 71654-EN (TGAI):**

- a. Submit s CAS Registry numbers for all ingredients on the CSF. The must be placed after the component descriptor.
- b. All impurities potentially present at >0.1% must be identified individually on the CSF (ie. [REDACTED], etc?) and have upper certified limits calculated.
- c. The information on the top row of the CSF where refined oil of *Nepeta cataria* is identified as "active technical grade" should be deleted.
- d. The parentheses around the amounts of the remaining ingredients provided in column 13b of the CSF must be deleted.

- e. The identity of the active ingredients given on the CSF and the product label must be made consistent.
- f. The certified limits are in excess of what is recommended in 40CFR 158.175(b)(2) and ranges determined in preliminary analyses. Please base the certified limits on that presented in the 40 CFR or provide justification for deviations. EPA would like to note that [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED] EPA considers this range satisfactory for regulatory purposes because the component is undetectable in the final EP products.
- g. The lower certified limits for impurities, un-reacted starting materials, etc. must be deleted.
- h. The proposed Upper certified limit for [REDACTED] should be revised to reflect the upper part of the range described in preliminary analyses [REDACTED] EPA considers this satisfactory for regulatory purposes because the component is undetectable in the final EP products.
- i. The proposed upper certified limit for [REDACTED]  
[REDACTED]  
[REDACTED]). EPA considers these upper limits to be satisfactory, considering the variation present in source material supply, source material composition, the negligible amount of these components in EP products, [REDACTED]  
[REDACTED] and the anticipation that no additional toxicity (other than that already associated with dihydronepetalactone) will be associated with these components.
- j. Following the addition of other ingredients to the CSF, the please ensure that the percent (%) by weight totals = 100%.
- k. Please complete blocks #5. and #6. on the CSF.

**EPA File Symbol 71654-EG (7% Lotion)**

- a. Provide a complete address and CAS registry number for the component [REDACTED]
- b. Please change the CAS No. for [REDACTED] and for [REDACTED]

c. Please provide a CAS No. for the active ingredient.

d. [REDACTED]  
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[REDACTED] are not on the most recent on-line inert ingredients list (August 2004). Please provide alternate components that are on the EPA inert ingredients list or provide information to the inert ingredients branch (IIAB) for listing these (contact in IIAB - Kerry Leifer, leifer.kerry@epa.gov).

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[REDACTED] given on the CSF does not match the content given in MRID 47003301.

g. Please address the discrepancy of why the supplier for [REDACTED]  
[REDACTED] given on the CSF does not match the supplier given in MRID 47003301.

h. Please complete blocks 5. and 6. of the CSF.

**EPA File Symbol 71654-ER (15% Lotion)**

a. The same conditions and concerns reported for the 7% lotion (above) apply for the 15% lotion.

**II. PRODUCT CHEMISTRY**

**File Symbol 71654-EG (7% Lotion)**

a. Please provide a rationale for the increase in percent weight of [REDACTED] in the 7% lotion when compared to the TGAI.

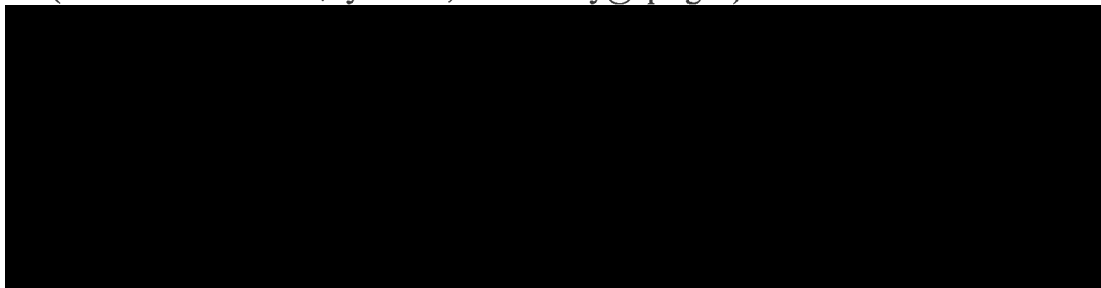
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c. Submit quality control procedures for the formulation process.

d. Please address the observation that extended storage at ambient conditions (25°C and 60% RH) results in the degradation of dihydronepetalactone and other components.

e. Please submit information regarding the following inert ingredients (below) that are not on the most recent EPA inert ingredients list (August 2004).

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- c. Please address stability in the presence of different temperatures and metals by discussing the relative impacts that packaging and storage will have on the stability of the product.
- d. Please provide a method for the determination of density.

**File Symbol 71654-EG (7% Lotion)**

- a. Please address oxidation/reduction: chemical incompatibility and explodability.
- b. Submit storage stability and corrosion characteristics tests upon their completion.

**File Symbol 71654-ER (15% Lotion)**

- a. The same deficiencies outlined for the 7% lotion (above) apply for the 15% lotion.

2. Tier I Toxicity studies are **ACCEPTABLE**.

3. Tier I Non-Target studies have not been submitted by the registrant. EPA expects that the use pattern of this product as an insect repellent will preclude significant adverse exposure to

nontarget organisms. EPA will therefore, waive the testing guideline for Tier I non-target toxicity applicable to TGAI.

#### **IV. PRODUCT PERFORMANCE**

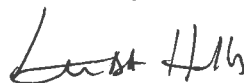
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Sincerely,



Linda Hollis., Chief  
Biochemical Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460**

**OFFICE OF PESTICIDES AND TOXIC SUBSTANCES**

**MEMORANDUM**

**DATE:** October 4, 2007

**SUBJECT:** Science Review and Human Health Risk Assessment in Support of the Registration of the Insect Repellent Refined Oil of *Nepeta cataria* (TGAI), and two lotion end-use products.

**Decision Nos.:** 371861, 372756, 371862  
**DP Nos.:** 338556, 339493, 339547  
**EPA File Symbol:** 71654-EN (TGAI), 71654-EG  
(7% a.i.), 71654-ER (15% a.i.)

**PC Code:** 004801  
**MRID Nos.:** 469773-01 through -06;  
469774-01 through -14, -20 & -22;  
470031-02 & -05; 470156-01 & -02

**FROM:** Roger Gardner, Senior Scientist  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511P)

**TO:** Raderrio Wilkins, Regulatory Action Leader  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511P)

\*\*\*\*\*~~CONTAINS CONFIDENTIAL BUSINESS INFORMATION~~\*\*\*\*\*

**ACTION REQUESTED:** Review of scientific information submitted by E.I. du Pont de Nemours and Company to support registration of Refined Oil of *Nepeta cataria* (71654-EN) as a dermally applied insect repellent in a 7% Lotion (71654-EG) a 15% Lotion (71654-ER).

**RECOMMENDATIONS AND CONCLUSIONS**

There are adequate data for conducting a risk assessment that supports registration of the insect repellent Refined Oil of *Nepeta casaria* and the 7% and 15% lotion products. Specific conclusions and recommendations are summarized as follows:

1. The active ingredient is classified into Toxicity Category III for oral toxicity and primary eye irritation and Toxicity Category IV for dermal, inhalation and skin irritation. It is not a skin sensitizer.
2. The lotion formulations containing 7 and 15% active ingredient are classified into Toxicity Category IV for oral and dermal toxicity as well as eye and skin irritation and they are not skin sensitizers.
  - a. The acute inhalation study for the 15% lotion was waived on the basis of the lack of inhalable particles and viscosity of the formulation.
  - b. The acute toxicity data for the 15% formulation are used to support registration of the 7% lotion.
3. In the acute neurotoxicity study, behavioral effects (decreased motor activity) were noted in rats after a single oral dose of 200 mg active ingredient per kg body weight, and effects were temporary with treated rats adapting to the neurological effects after repeated dosing in other studies.
4. The subchronic oral toxicity study in rats demonstrated a no-observed-effect level (NOEL) of 200 mg/kg/day and a lowest-observable-effect level (LOEL) of 1000 mg/kg/day based on the increased incidence of minimal to mild degeneration/regeneration of the olfactory epithelium lining the nasal turbanates of treated male and female rats.
5. No systemic toxicity was observed in the subchronic dermal toxicity study at dose levels up to 1000 mg/kg/day.
6. No adverse effects were observed in a 28-day oral immunotoxicity study or in a developmental toxicity study at oral doses up to 1000 mg/kg/day.
7. No genetic toxicity was observed in bacteria (point mutation assay), an in vitro cytogenetics assay, or in a mouse micronucleus assay. However, a point mutation assay in mouse lymphoma cells reported an increased frequency of point mutations at doses approaching cytotoxic levels without metabolic activation. These results should be confirmed with another assay in a mammalian cell system.
8. An in vitro dermal penetration study indicated that human skin is relatively impermeable (2% of the applied dose) compared to rat skin (78% of the applied dose).

9. Since there were no endpoints indicated in the subchronic dermal toxicity study, and since human skin is relatively impermeable, no endpoints were selected for risk characterizations. The acute neurotoxicity endpoint is appropriate to an incidental oral exposure for children, but because the effect is reversible and pharmacological in nature (reduced activity) and because the label contains instructions to avoid incidental exposure (i.e., licking of fingers and hands), no risk characterization was done for incidental oral scenarios.
10. The only data gap is for a confirmatory gene mutation assay in mammalian cells to determine reproducibility and/or reduce uncertainty associated with the positive results in the mouse lymphoma assay.

## I. CHEMICAL AND PRODUCT IDENTITY

### A. Background

The active ingredient is a refined, multi-component extract of *Nepeta cataria* which is a member of the mint family of plants (Labiatae). The technical grade active ingredient (TGAI) is identified on proposed product labels as Refined Oil of *Nepeta cataria* and is also referred to as hydrogenated catmint oil (HCO). The plant is commonly known as catnip and is indigenous from eastern Mediterranean to eastern Himalayan regions. The perennial herb can also be grown in North America. Therefore, general information on the nature of the active ingredient is readily available (e.g., <http://chemistry.about.com/library/weekly/aa103001a.htm>; accessed on October 2, 2007) and is summarized as background below.

Nepetalactone is the major component of the refined oil, but there are other components such as pulegic acid with known insect repellent activity. Nepetalactone is a terpene comprised of two isoprene units, and it has a chemical structure similar to that of the valepotriates (from the herb valerian) which have mild central nervous system effects in humans (sedative or stimulant depending on the individual).

The feline behavioral effects of the nepetalactone in catnip are well known, but not all cats respond to the activity of the oil; their sensitivity is inherited (an autosomal dominant gene). Sensitive kittens do not develop responsiveness until they are 3 months old, and young kittens have been known to exhibit avoidance behavior. The variety of responses includes rubbing of the head, chin, cheek or body as well as head shaking or rolling. Sensitive cats may also lick or chew the plant or other source of nepetalactone. These reactions are temporary and can not be induced for an hour or more after exposure. Individual responses vary among sensitive cats. Since the feline receptors for nepetalactone are located in the vomeronasal organ above the cat's palate, the response is associated with the inhalation route of exposure.

Refined Oil of *Nepeta Cataria*  
PC Code: 004801

DP Number: 338556, 339493, 339547  
EPA File Symbol Number: 71654-EN, 71654-EG, 71654-ER

Historically, catnip has been used in herbal medicine to treat fever, head and tooth aches, colds, colic and spasms in humans. In some individuals catnip can be used to induce sleep, but it can also act as a stimulant in others. At high doses it is emetic in cats and humans. Other historical uses included rubbing meat with catnip leaves, adding it to salads or making tea with it.

Refined Oil of *Nepeta cataria* is being formulated into two lotion products for direct application to human skin to repel biting flies, mosquitoes and other insects. The two concentrations of the active ingredient proposed for these uses are 7% and 15%.

#### B. Physical and Chemical Properties (Table 1)

The principal insect repellent components in Refined Oil of *Nepeta cataria* are dihydronepetalactone (69.99% w/w) and pulegic acid (6.77% w/w).

**Table1: Physical and Chemical Properties for Refined Oil of *Nepeta cataria*<sup>a</sup>**

Guideline Reference No./Property	Description of Result	Methods
830.6302 Color	Yellow @ 21°C	CCL SOP 10.11
830.6303 Physical State	Liquid @ 21°C	CCL SOP 10.12
830.6304 Odor	Minty	CCL SOP 10.13
830.6313 Stability	Stable @ room and elevated temperatures and in the presence of metals and ions	OPPTS 830.6313
830.6314 Oxidation/Reduction: Chemical Incompatibility	Dihydronepetalactone was relatively stable in solution with metals and metal salts after 14 days at 25°C, with slight decreases at 54°C after 14 days.	
830.6315 Flammability	>99°C	CCL SOP 10.18
830.6316 Explodability	<b>Not addressed</b>	
830.6317 Storage Stability	In short-term testing at 25 and 54°C, dihydronepetalactone content was relatively stable. Guideline study is in progress.	
830.6319 Miscibility	Not applicable, product is not to be diluted in petroleum solvents	
830.6320 Corrosion Characteristics	Guideline study is in progress	
830.6321 Dielectric Breakdown Voltage	Not applicable, product is not for use around electrical equipment	
830.7000 pH	3.97 @ 25°C (1% w/w in deionized water)	CCL SOP 10.17
830.7050 UV/Visible Absorption	Not applicable,	
830.7100 Viscosity	18.09 mm <sup>2</sup> /s (cSt) @ 22°C	ASTM D 445 and D446
830.7200 Melting Range	Not applicable, product is a liquid	
830.7220 Boiling Range	266.0 ± 12.0°C	Mettler FP900 Thermosystem
830.7300 Density/Relative Density/Bulk Density	1.0334 @ 20.7°C	<b>Not provided</b>
830.7370 Dissociation Constant in Water	Not applicable, required only for pure active ingredient	
830.7550 Partition Coefficient	Not applicable, required only for pure active ingredient	
830.7840 Water Solubility	0.254 ± 0.013 g/L @ 30°C	OPPTS 7840
830.7950 Vapor Pressure	591, 707, 907, 1100, 1320, and 1630 Pa @ 20, 25, 30, 35, and 40°C, respectively	Terranova 722A diaphragm gauge controller

<sup>a</sup>Data from MRIDs 46977420, 46977422, 47003102, 47003105

### C. Use Pattern

End-use product labels include the following instructions for use:

Dispense a small amount of lotion directly onto skin. Spread uniformly to completely cover any exposed skin surface. Reapplication after six hours may be necessary. When applying to children, dispense into an adult's hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands.

Do not apply over cuts or damaged skin.

The signal word on the label is CAUTION, and other precautionary statements regarding hazards to humans and domestic animals include:

- Keep out of reach of children.
- Avoid contact with eyes.

First aid statements on the label are as follows:

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
If in Eyes: <ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after five minutes, then continue rinsing eye.</li><li>• Call a Poison Control Center or doctor for further treatment advice.</li></ul>
If a reaction to this product is suspected: <ul style="list-style-type: none"><li>• Discontinue use.</li><li>• Take off contaminated clothing.</li><li>• Wash skin thoroughly with plenty of water.</li><li>• Call a Poison Control Center or doctor for further treatment advice.</li></ul>
If Swallowed: <ul style="list-style-type: none"><li>• Call Poison Control Center or doctor immediately for treatment advice.</li><li>• Do not induce vomiting unless told to do so by the poison control center or doctor</li><li>• Do not give anything by mouth to an unconscious person</li></ul>

## II. TOXICITY OF THE TGA I

### A. Acute Toxicity

#### 1. Active ingredient (Table 2)

In the acute oral toxicity study (MRID 46977401), one rat dosed at 1750 mg/kg and two dosed at 5000 mg/kg died or were sacrificed for humane reasons on the day of dosing. A surviving rat given 550 mg/kg exhibited no clinical signs of toxicity. Wet fur, lethargy, ataxia, partially closed

or dark eyes, slow or labored breathing, prostrate posture, lacrimation, stained fur/skin, dark extremities, and/or moribundity were noted on the other rats with recovery of the survivors by day 3 of observation.

Ataxia was noted during exposure or immediately after test material removal in the acute dermal toxicity study (MRID 46977402). Wet fur of the inguinal region, leaning, high carriage, absent feces, labored breathing, lethargy, lacrimation, not eating, and/or stained fur around face, perineum, inguen, or abdomen were noted with recovery by day 6 post-dosing.

Male rats in the inhalation study (MRID 44677406) exhibited lethargy, labored breathing and/or hunched posture immediately following exposure. Colored nasal discharge was noted from three males one day post-exposure with recovery by day 3. Lethargy, labored breathing, gasping, hunched posture, incoordination, and/or prostration were noted from two female rats immediately following exposure with recovery by day 4. Colored nasal, oral, or ocular discharge was noted from two females one day post-exposure with recovery by day 7 of observation.

**Table 2: Acute Toxicity Profile – Hydrogenated Catmint Oil**

Study Type (Guideline)	Species	Results	Toxicity Category	MRID
Acute oral (870.1100)	Rat	LD <sub>50</sub> = 1750 (95% C.L. 455.5-9230) mg/kg (females using the Up-and Down Method)	III	46977401
Acute dermal (870.1200)	Rat	LD <sub>50</sub> > 5000 mg/kg for males, females, and for both sexes combined.	IV	46977402
Acute inhalation (870.1300)	Rat	LC <sub>50</sub> > 5.5 mg/L (males, females, and both sexes combined; 4 hour nose-only exposure)	IV	46977406
Primary eye irritation (870.2400)	Rabbit	Corneal opacity persisted for 24 to 48 hours after treatment with clearance by 72 hours. Iritis was noted at 1 and 24 hours after treatment and cleared by the 48 hour observation. Conjunctival irritation was noted on one rabbit one hour throughout 48 hours after treatment with clearance by 72 hours. The maximum average score was 24.0 at 24 hours after test material instillation. Hydrogenated Catmint Oil was mildly irritating.	III	46977403
Primary dermal Irritation (870.2500)	Rabbit	No dermal irritation or clinical signs of toxicity were observed during the study. The primary irritation index was 0.0.	IV	46977404
Dermal sensitization (870.2600)	Mouse	A local lymph node assay (LLNA) indicated that hydrogenated catmint oil is not a dermal sensitizer.	---	46977405

## 2. Acute toxicity of the lotion products (Table 3)

A battery of six acute toxicity studies on the 15% lotion indicated the following profile:

**Table 3: Acute Toxicity Profile – 15% Hydrogenated Catmint Oil Lotion**

Study Type (Guideline)	Species	Results	Toxicity Category	MRID
Acute oral (870.1100)	Rat	LD <sub>50</sub> > 5000 mg/kg (females using the Up-and Down Method)	IV	46977301
Acute dermal (870.1200)	Rat	LD <sub>50</sub> > 5000 mg/kg for males, females, and for both sexes combined.	IV	46977302
Acute inhalation (870.1300)	Rat	The registrant is seeking to waive the requirement for an acute inhalation test. The rationales are: 1) its intended use as an insect repellent lotion for direct application is to the skin, 2) its high viscosity as an oil-water emulsion, and 3) the low vapor pressure and low toxicity of the active ingredient	---*	46977303
Primary eye irritation (870.2400)	Rabbit	Corneal opacity, iritis, or positive conjunctival irritation were not noted on any rabbit during the study. The maximum average score was 4.7 at one hour after test material instillation..	IV	46977303
Primary dermal Irritation (870.2500)	Rabbit	Well defined erythema was noted on 2/3 rabbits one hour after patch removal with reduction to very slight erythema by 24 and 48 hours that cleared by 72 hours. Well defined erythema was noted on another rabbit one hour after patch removal with persistence through 24 hours, reduction to very slight erythema by 48 hours, and clearance by 72 hours.	IV	46977304
Dermal sensitization (870.2600)	Mouse	A local lymph node assay (LLNA) indicated that lotion I is not a dermal sensitizer.	---	46977305
*This data requirement has been waived on the basis of the rationale presented by the Registrant.				

A second product containing 7% active ingredient is also being proposed for registration. No data on that product have been submitted, but the data summarized above will support the second product because the composition of both products is substantially similar (i.e., both products contain the same inert ingredients) based on review of confidential statements of formula (CSF).

## 3. Acute Neurotoxicity (OPPTS 870.6200)

In an acceptable acute neurotoxicity study (MRID 46977409), groups 12 male or 12 female rats were given a single oral dose of hydrogenated catmint oil (>99% by weight) in corn oil at 0, 40, 200 or 1000 mg/kg body weight. Neurobehavioral assessment (functional observational battery [FOB] and motor activity testing) was performed on all animals pre-dosing and on the day of dosing as well as 7 and 14 days after dosing. Body weight and food consumption were measured weekly throughout the study. At study termination, 6 animals/sex/group were euthanized and

perfused *in situ* for neuropathological examination. Those animals from the control and high dose groups were subjected to histopathological evaluation of central and peripheral nervous system tissues.

No deaths or clinical signs of toxicity were observed and body weight, body weight gain and food consumption were unaffected by treatment. Selected functional observational battery (FOB) results are summarized in Table 4 as follows:

Table 4: Selected FOB results		
Observation	Incidence (number affected/number evaluated)	
	Controls	1000 mg/kg
Males		
Unbalanced swaying and/or uncoordinated gait		
In home cage	0/12	2/12
In open field	0/12	3/12
Abnormal posture	0/12	11/12
Low Arousal	0/12	4/12
No reaction to auditory stimulus	0/12	2/12
Females		
Curled-up posture	1/12	9/12
Appeared to be sleeping	0/12	3/12
Unbalanced swaying and/or uncoordinated gait		
In home cage	0/12	4/12
In open field	0/12	3/12
Slow righting reflex	0/12	11/12
Lacrimation	0/12	2/12
Ataxic gait	0/12	4/12
Low arousal	0/12	2/12
No reaction to auditory stimulus	0/12	8/12
Walking on toes	0/12	2/12

Following the motor activity evaluation, 1/12 males and 1/12 females at 1000 mg/kg vs. none of the controls had slow and/or no pupillary response. Mean hindlimb foot splay was significantly increased in males (33% higher) and females (30% higher) at 1000 mg/kg. Mean body temperature was decreased in males (4% lower) and females (7% lower) at 1000 mg/kg.

On day 1, the cumulative (total) duration of movement was decreased in males and females at 200 mg/kg (19-20%) and 1000 mg/kg (48-52%); the changes were statistically significant in males and females at 1000 mg/kg. The cumulative number of movements on day 1 was decreased in males and females at 200 mg/kg (9-24%) and 1000 mg/kg (35-41%); only the difference in females at 1000 mg/kg was statistically significant.

**The LOAEL for acute neurotoxicity of hydrogenated catmint oil in rats was 200 mg/kg based on decreased motor activity on the day of dosing in males and females. The NOAEL was 40 mg/kg.**

## B. Subchronic Toxicity

### 1. Oral Toxicity (OPPTS 870.3100)

In an acceptable oral toxicity study (MRID 46977407), hydrogenated catmint oil (HCO) was administered by gavage daily to groups of ten rats/sex at doses of 0, 40, 200, or 1000 mg/kg body weight for 93 days. Hematological, clinical chemistry, urinalysis, ophthalmoscopic, neurological, and microscopic tissue and organ effects were determined only in the subchronic studies.

All rats in the study survived until scheduled sacrifice. The only persistent clinical observation reported was perineal staining throughout the study on three female high-dose rats. No neurological or ophthalmoscopic effects were noted. Total body weight gain was decreased 12% and food efficiency decreased 14% in male rats treated with 1000 mg/kg dose during the study; but no treatment-related effects were found in the remaining groups.

No treatment-related hematological effects were found during the subchronic study. Total bilirubin was slightly increased in high-dose male rats and cholesterol was slightly increased in high-dose male and female rats on study days 48/49 and 92/93; consistent with slight hepatic congestion. Total urine protein was increased on days 48 and 92 and granular casts were observed on day 92 in all male treatment groups. No increase in urine protein or cast formation was found in female rats.

Centrilobular hepatocellular hypertrophy was statistically significantly increased in male and female rats at the 200 and 1000 mg/kg/day dose level.

A dose-related increase in the incidence and severity of hyaline droplet formation within the epithelium of the proximal convoluted tubule was found in all treatment groups of male rats. In addition, a minimal to mild increase in the incidence of eosinophilic granular casts concomitant with the hyaline droplet formation was found. The casts consisted of multiple focal accumulations of granular material in the tubular lumen near the junction of the inner and outer stripes of the renal medulla. An associated increase in the incidence and severity of minimal to moderate chronic progressive nephropathy was also observed in high-dose male rats.

Minimal to mild degeneration/regeneration of the olfactory epithelium lining the nasal turbinates was observed in high-dose male and female rats. This lesion was characterized by multifocal hypercellularity in the olfactory epithelium at nose levels III and IV due to regeneration of sensory cell nuclei and degeneration of sustentacular cells. In some areas, the olfactory epithelium was thinner than normal but sensory cell nuclei predominated. Sensory or sustentacular

cell necrosis was not apparent and there was no exfoliation of the epithelium or associated inflammation.

**The LOAEL for refined oil of *Nepetea cataria*, hydrogenated catnip oil, for male and female rats is 1000 mg/kg/day based on treatment-related effects to the olfactory epithelium. The NOAEL is 200 mg/kg/day for male and female rats.**

## 2. Dermal Toxicity (OPPTS 870.3220)

In an acceptable 28-day dermal toxicity study (MRID 46977415), HCO (purity >99%), was applied to the shaved skin of groups of 10 male and 10 female rats at doses of 0, 100, 500, or 1000 mg/kg/day six hours/day for 29 days.

All rats survived until scheduled sacrifice and no treatment-related effects were found on body weight, body weight gain, food intake, food efficiency, hematology, or clinical chemistry of treated male and female rats. No neurotoxicity was observed.

Treatment-related effects were found only in male rats of all groups and were consistent with hyaline droplet formation. Urine protein excretion was increased 80, 80, and 131% in the low- to high-dose male rats, respectively, and male rats had an increase in urine white blood cells (2/10, 6/10, 9/10, and 9/10, in the control through high-dose group, respectively) and in finely granular casts (0/10, 1/10, 3/10, and 8/10, respectively).

The absolute and relative liver weights of male rats treated with  $\geq 500$  mg/kg/day were increased 10 – 20% and absolute and relative kidney weights were increased 7-15% in male rats treated with  $\geq 100$  mg/kg/day. A dose-related increase in minimal to mild hyaline droplet formation within the epithelium of the proximal convoluted tubule was observed microscopically in all groups of treated male rats (0/10, 3/10, 9/10, and 10/10 for the control through high-dose groups, respectively). No treatment-related effects were observed microscopically in the liver; however, the increased absolute and relative liver weights were consistent with hypertrophy.

Very slight to moderate erythema was noted on some animals at the treatment site early in the study, but resolved on all by Day 12. No edema was observed. Epidermal scaling, hyperkeratosis, and epidermal sloughing were also observed at necropsy, but the effects were unrelated to dose.

**The dermal LOAEL for male and rats treated with HCO for 29 days was not established in this study. The NOAEL is the highest dose tested, 1000 mg/kg bw/day.**

### C. Immunotoxicity (OPPTS 870.7800)

In an acceptable immunotoxicity study (MRID 46977407), groups of ten rats/sex were treated by gavage with daily doses of 0, 40, 200, or 1000 mg HCO/kg body weight for 28 days. An additional groups of ten rats/sex received saline (negative control) or 20 mg/kg cyclophosphamide (positive control) daily. On the 22<sup>nd</sup> day of treatment, all test animals were given an intravenous injection containing sheep red blood cells (SRBC), and at the end of the study, sera were collected and subjected to an enzyme-linked immunosorbent assay (ELISA) to determine if the test material suppressed an immune response.

No effects on humoral immune function were found in HCO-treated male and female rats. All test animals survived until scheduled sacrifice. No neurological, ophthalmoscopic, or other toxicity was noted.

**The LOAEL for HCO in male and rats was not established for effects on humoral immune function. The NOAEL for male and female rats was the highest dose tested, 1000 mg/kg/day.**

### D. Developmental Toxicity (OPPTS 870.3700)

In an acceptable developmental toxicity study (MRID 46977408), HCO (>99%) was administered by gavage to groups of 22 time-mated female rats at doses of 0, 200, 500 or 1000 mg/kg/day in corn oil on gestation days 6 through 20. On gestation day 21 (GD 21), all dams were euthanized and a gross external and visceral examination was performed. The uterus of each pregnant female was removed and the uterine contents were examined and described. All fetuses were removed and individually identified, weighed, sexed, and examined for external and skeletal alterations; approximately one half of the fetuses were examined for visceral and head abnormalities. The total number of fetuses examined (number of litters) was 259 (21), 275 (22), 285 (22), and 256 (21) for the 0, 200, 500, and 1000 mg/kg/day groups, respectively.

There were no treatment-related adverse effects in survival, clinical signs, body weight, or cesarean parameters. Maternal toxicity was limited to reductions in body weight gain (27% and 54%, respectively) and food consumption (~10%) during the first two days of dosing at 500 and 1000 mg/kg/day. These reductions were not considered adverse since they were transient and had no significant impact on overall body weight gain or food consumption for the entire gestation period. Stained fur was observed in the 1000 mg/kg group and was considered possibly test substance-related but not adverse.

**Based on the results of this study, the oral maternal toxicity LOAEL for hydrogenated catmint oil in rats was not identified. The maternal NOAEL is 1000 mg/kg bw/day.**

There were no treatment-related adverse effects in developmental parameters (deaths/resorptions, fetal weight, developmental alterations) at any dose level tested. Developmental variations common to this strain of rat were observed in the treated and control groups at a similar incidence. No treatment-related malformations were seen.

**The oral developmental toxicity LOAEL for hydrogenated catmint oil in rats was not identified. The developmental NOAEL is 1000 mg/kg bw/day.**

#### E. Genetic Toxicity

##### 1. Point mutation assay – bacteria (OPPTS 870.5100)

In an acceptable reverse gene mutation assay in bacteria (MRID 46977410), strains TA98, TA100, TA1535 and TA1537 of *Salmonella typhimurium* and strain WP2 *uvrA* of *Escherichia coli* were exposed to HCO (>99% a.i. by weight) dissolved in DMSO in two independent assays using a standard plate incorporation procedure and duplicate and triplicate plating in the first and second assays respectively. In the first mutagenicity assay, which was called the toxicity-mutation test, concentrations of 0, 33.3, 66.7, 100, 333, 667, 1000, 3333 or 5000 µg/plate were tested with and without S9-mix. In the second assay, which was called the mutagenicity test, concentrations of 0, 333, 667, 1000, 3333 or 5000 µg/plate were tested with and without S9-mix. The S9 fraction was obtained from Aroclor 1254-induced male Sprague-Dawley rat liver.

In the first assay, cytotoxicity was observed at the limit concentration in strain TA1537 both in the presence and absence of S9 mix as well as in strain TA1535 in the presence of S9 mix. In the second assay, cytotoxicity was observed at the limit concentration, and also at 3333 µg/plate, in strain TA1537 both in the presence and absence of S9 mix. Cytotoxicity never caused any more than a slight reduction in the background lawn. No precipitation was observed at any concentration level in either assay. The number of revertants per plate was not increased over the concurrent solvent control value at any test material concentration, with or without S9-mix, in any tester strain. The solvent and positive controls induced the appropriate responses in the corresponding strains. **There was no evidence of induced mutant colonies over background.**

##### 2. *In vitro* mammalian cell point mutation assay (OPPTS 870.5300)

In an acceptable mammalian cell gene mutation assay (MRID 46977413), L5178Y/TK+/- mouse lymphoma cells cultured *in vitro* were exposed for 4 hours to hydrogenated catmint oil (>99% a.i. by weight) dissolved in dimethyl sulfoxide at concentrations of 0, 100, 150, 200, 250, 300 or 350 µg/mL in the absence of mammalian metabolic activation and at concentrations of 0, 300, 350, 425, 500 or 600 µg/mL in the presence of mammalian metabolic activation (S9-mix with S9 fraction from livers of Aroclor 1254 induced male rats).

Hydrogenated catmint oil was tested up to concentrations limited by cytotoxicity, which was clearly demonstrated in a preliminary cytotoxicity assay. There was significant concentration-related cytotoxicity of hydrogenated catmint oil. In the preliminary cytotoxicity assay, precipitation of hydrogenated catmint oil in the culture medium was seen at the end of the 4-hour exposure only at the concentration of 4500 µg/mL, which was the highest concentration tested. Mutant frequencies were significantly increased in the absence of metabolic activation only. Two cultures had mutant frequencies of at least 100 mutants per 10<sup>6</sup> clonable cells above that of the solvent control, and that extent of an increase is considered biologically significant. Two other cultures, also in the absence of S9 mix, had mutant frequencies between 55 and 99 mutants per 10<sup>6</sup> clonable cells above that of the solvent control. There was a concentration-related increase in the mutant frequency in the absence of S9 mix. Analysis of colony size distributions showed an increase in the frequency of small colonies in the cultures treated with the test substance. Solvent and positive controls gave appropriate responses. **There was clear evidence of induced mutant colonies over background.**

3. *In vitro* mammalian cell chromosomal aberration assay (OPPTS 870.5375)

In an acceptable mammalian cell cytogenetics assay (MRID 46977411), cultured human peripheral blood lymphocytes were exposed for 4 hours to HCO (>99% a.i. by weight) dissolved in dimethyl sulfoxide (DMSO) at concentrations of 0, 50, 200 or 550 µg/mL without metabolic activation or at concentrations of 0, 210, 420 or 840 µg/mL with metabolic activation, and in both cases the treatment was followed by a 16-hour recovery period so that the total time to harvest was 20 hours after the initiation of treatment. In addition, other cells of this same type were exposed for 20 hours without any recovery period to the same test substance dissolved in DMSO at concentrations of 0, 37.5, 75 or 350 µg/mL without metabolic activation. Metabolic activation was provided by S9 mix with S9 fraction from livers of Aroclor 1254-induced male rats.

HCO was tested up to cytotoxic concentrations based on mitotic indices found in a preliminary cytotoxicity study and concurrently with the cytogenetic assay. At least in the cytogenetic assay, the mitotic index at the highest test concentration was reduced to less than half of that in the solvent control. There were no statistically significant increases over the solvent control values in the percentages of cells with structural aberrations including or excluding gaps at any test material concentration with or without S9-mix. Also there were no increases in numerical aberrations. There was no precipitation of the test substance. Solvent and positive control values were appropriate and within the testing laboratory's historical control ranges for structural chromosomal aberrations and numerical aberrations. **There was no evidence of chromosome aberrations induced over background.**

#### 4. *In vivo* mammalian chromosomal aberration test (OPPTS 870.5395)

In an acceptable mouse bone marrow micronucleus assay (MRID 446977412), groups of 10 mice/sex were given HCO (purity >99% by weight) in a single dose by gavage at 0, 500, 1000, or 2000 mg/kg body weight. Bone marrow cells were harvested from 5 mice/group at approximately 24 or 48 hours after the treatment. Two additional mice/sex/sacrifice time were treated at the highest dose level to observe toxicity and to be in reserve should some of the animals die before bone marrow could be harvested. Because no effect was seen on the frequency of micronucleated polychromatic erythrocytes at any dose of the test substance at 24 hours or at the highest dose at 48 hours, slides were not evaluated for the two lower doses at the 48-hour harvest time. The vehicle was corn oil.

At least one animal treated with HCO at every dose level showed symptoms of toxicity after administration in both the rangefinder experiment and the main experiment. At five and 15 minutes after treatment in the rangefinder experiment on males, all three animals showed ataxia, and two of them showed low posture 15 minutes after treatment. In the rangefinder experiment, no clinical signs of toxicity were observed at 30 or more minutes after treatment. In the main experiment at 2000 mg/kg bw, ataxia was seen in all 14 males and all 14 females, and prostration was observed in two females. At 1000 mg/kg bw, ataxia was seen in seven of the 10 animals treated of each sex, and at 500 mg/kg bw, ataxia was seen in one of the 10 animals treated of each sex. The only sign of moribundity or mortality of the test substance was the death of one female in the high dose group. Polychromatic erythrocytes (PCEs) were examined for micronuclei in five animals/sex/dose level. PCEs were similarly examined in the vehicle control and in the positive control, cyclophosphamide. The vehicle and positive control treatments were also made by oral intubation, and the positive control was examined only at the 24-hour harvest time. Hydrogenated catmint oil was tested at an adequate dose, which was the limit dose for the assay. The positive control induced the appropriate response. There were no statistically significant changes seen in the PCE:NCE ratio. **There was not a significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow after any treatment time.** It was concluded that the test chemical was negative in this *in vivo* study.

### III. DOSE-RESPONSE ASSESSMENT (Table 5)

Table 5: Toxicity Profile for Hydrogenated Catmint Oil				
Study Type (Guideline)	Species	Dose-Response Information	Effects	MRID
Acute Neurotoxicity (870.6200)	Rat	<b>Doses tested:</b> 0, 40, 200 & 1000 mg/kg <b>NOAEL</b> = 40 mg/kg <b>LOAEL</b> = 200 mg/kg	Decreased motor activity on the day of dosing in males and females	45977409

**Table 5: Toxicity Profile for Hydrogenated Catmint Oil**

Study Type (Guideline)	Species	Dose-Response Information	Effects	MRID
Subchronic Oral Toxicity (870.3100)	Rat	<b>Doses tested:</b> 0, 40, 200 & 1000 mg/kg/day <b>NOAEL</b> = 200 mg/kg <b>LOAEL</b> = 1000 mg/kg	Minimal to mild degeneration / regeneration of the olfactory epithelium lining the nasal turbinates of males and females	46977407
Subchronic Dermal Toxicity (870.3200)	Rat	<b>Doses tested:</b> 0, 100, 500 & 1000 mg/kg <b>NOAEL</b> = 1000 mg/kg <b>LOAEL</b> > 1000 mg/kg	No adverse effects were reported.	46977415
Oral Immunotoxicity (870.7800)	Rat	<b>Doses tested:</b> 0, 40, 200 & 1000 mg/kg/day <b>NOAEL</b> = 200 mg/kg <b>LOAEL</b> = 1000 mg/kg	No effects reported	46977407
Oral Developmental Toxicity (870.3700)	Rat	<b>Doses tested:</b> 0, 100, 500 & 1000 mg/kg/day <u>Maternal Toxicity</u> <b>NOAEL</b> = 1000 mg/kg <b>LOAEL</b> > 1000 mg/kg <u>Developmental Toxicity</u> <b>NOAEL</b> = 1000 mg/kg <b>LOAEL</b> > 1000 mg/kg	<u>Maternal Toxicity</u> No adverse effects were reported. <u>Developmental Toxicity</u> No adverse effects were reported.	46977408
Reverse Mutation Assay (870.5100)	Bacteria	<b>Doses tested:</b> 0 to 5000 µg/plate with or without metabolic activation (S9 mix)	Negative	46977410
Mammalian cell gene mutation assay (870.5300)	Mouse lymphoma cells	<b>Doses tested:</b> 0 to 3500 µg/mL without metabolic activation (S9) or 0 to 600 µg/mL with metabolic activation (S9 mix)	Mutagenic at doses approaching or at cytotoxic levels without metabolic activation (250 to 350 µg/mL)	46977413
<i>In vitro</i> cytogenetics assay (870.5375)	Human peripheral blood lymphocytes	<b>Doses tested:</b> 0, 50, 200 or 550 µg/mL without metabolic activation or 0, 210, 420 or 840 µg/mL with metabolic activation	Negative	46977411
Bone marrow micronucleus assay (870.5395)	Mice	<b>Doses tested:</b> 0, 500, 1000, or 2000 mg/kg (single oral gavage doses)	Negative	4677412

## A. Endpoint Discussion

### 1. Acute Endpoints

Results of the acute oral toxicity study with the active ingredient (MRID 46977401) characterized effects at higher single oral doses as follows:

Death occurred on the day of dosing in one of the three rats dosed at 1750 mg/kg and one of two rats dosed at 5000 mg/kg. The remaining rat dosed at 5000 mg/kg was sacrificed for humane reasons on the day of dosing. No clinical signs were observed in the rat at 550 mg/kg. Clinical signs observed in the remaining rats included wet fur, lethargy, ataxia, partially closed or dark eyes, slow or labored breathing, prostrate posture, lacrimation, stained fur/skin, dark extremities, and/or moribundity. No clinical signs were observed by test day 3 (in surviving rats). No body weight losses occurred after dosing. No gross lesions were present in the rats at necropsy.

The only clinical sign noted in an acute oral toxicity study with the 15% lotion (MRID 46977301) was "high carriage" in one of three rats given the 5000 mg/kg dose. No other effects on body weight or incidence of gross lesions were noted in the study.

Dermal application of 5000 mg/kg to a group of 5 male rats had no effects, but the same dose applied to skin of 5 female rats had effects described in the study report (MRID 46977402) as follows:

The female rats exhibited lethargy, ataxia, absent feces, labored breathing, lacrimation, stained fur/skin, wet fur, not eating, high carriage, and/or leaning. Ataxia was observed only during the exposure period or immediately after test substance removal. The remaining clinical signs cleared by test day 6.

No clinical signs of toxicity were observed in male and female rats dermally exposed to 5000 mg of the 15% lotion per kg body weight (MRID 46977302).

After a 4-hour nose only exposure of 5 male and 5 female rats to air containing 5.5 mg HCO/L, clinical signs were described (MRID 46977406) as follows:

All animals...survived the exposure and the subsequent recovery period...

Notable clinical signs of toxicity...included lethargy, labored breathing, gasping, hunched or prostrate posture, and incoordination immediately following exposure which lasted for 1 to 3 days postexposure for males and females, respectively...

It should be noted that clinical signs similar to those described in acute toxicity studies were reported in the 90-day subchronic oral toxicity study (MRID 46977407). These effects were described as follows:

At 200 mg/kg/day, two males (of 10) were lethargic on the second day of dosing. At 1000 mg/kg/day, nine males and eight females were lethargic and four males and one female were ataxic during this period. All of these post-dosing observations were transient in that they resolved prior to the next dose and were not observed beginning on dosing day 3 through the end of the study.

At similar low doses, an acute neurotoxicity endpoint of 40 mg/kg was characterized by decreased motor activity on the day of dosing. These effects were not observed after repeated oral doses at similar levels, and no histopathology was found in nervous tissues from treated animals in the acute or subchronic neurotoxicity studies. In addition, the subchronic dermal toxicity study did not present histopathological effects in the nasal cavity or changes in neurological parameters after repeated dermal exposures up to 1000 mg/kg/day.

These studies indicate:

- The clinical signs observed at lethal oral doses (1750-5000 mg/kg) are not seen at single doses that are 3 to 10-fold lower (550 mg/kg) which suggest a steep dose-response curve.
- Acute oral toxicity study results with the 15% lotion appears to reduce the likelihood that neurological clinical signs will occur
- Acute studies by dermal or inhalation routes also appear to reduce the chances of seeing the clinical signs of concern.
- Lower non-lethal doses (200-1000 mg/kg) decreased motor activity, and results from subchronic studies suggest the effects are reversible and that rats can adapt to these effects even when dosing is continued.

**Therefore, the acute neurotoxicity NOEL is appropriate only in the assessment of incidental oral exposure scenarios for the insect repellent products considered in this assessment.**

## 2. Subchronic Endpoints

Effects noted in the subchronic oral toxicity study showed adaptive changes in the liver (centrilobular hepatocellular hypertrophy) and a sex-related (males only) species specific (rats) kidney effects (hyaline droplet formation and associated nephropathy) at the highest dose tested (1000 mg/kg/day). The 1000 mg/kg/day dose level was associated with significant degenerative/regenerative changes in the nasal cavity of treated rats, and the NOEL was 200 mg/kg/day. **Because no similar toxicity was observed in the 280-day dermal toxicity study, the 1000 mg/kg/day NOEL will be used to assess short and intermediate-term dermal exposures to the insect repellent products.**

No developmental toxicity or immunotoxicity was noted in rat studies using the same dose levels as those used in subchronic toxicity studies.

#### IV. Exposure Assessment

##### A. Use Patterns and Appropriate Endpoints

As indicated previously, the two lotion product labels include the following instructions for use:

Dispense a small amount of lotion directly onto skin. Spread uniformly to completely cover any exposed skin surface. Reapplication after six hours may be necessary. When applying to children, dispense into an adult's hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands.

Do not apply over cuts or damaged skin.

The products contains 7 or 15% active ingredient, and the application rate is based on dosimetry information reported in product performance studies (MRID 47015602). The application rates are determined as follows:

$$0.63 \text{ g product}/250 \text{ cm}^2 \text{ for 15\% lotion} = 2.52 \text{ mg product}/\text{cm}^2$$

$$(2.52 \text{ mg}/\text{cm}^2)(0.15) = 0.378 \text{ mg active ingredient}/\text{cm}^2$$

The endpoints appropriate for this type of insect repellent use are as follows:

**Endpoint Summary**

Scenario	Study Type	NOEL/LOEL	Effects	MRID
Acute (Incidental Oral)	Acute Neurotoxicity	40/200 mg/kg	Deceased motor activity on the day of dosing in males and females	45977409
Short- & Intermediate Term	28-Day Dermal Toxicity	≥1000 mg/kg/day	No adverse effects noted.	46977415

NOEL = no-observed-effect level; LOEL = lowest-observed-effect level.

No uncertainty factors are specified because:

- Labeling cautions against application of products to the hands of children or allowing children to apply the lotions themselves, and
- Subchronic dermal toxicity studies did not indicate systemic toxicity after repeated exposure to a limit dose of 1000 mg/kg/day.

##### B. Dermal Penetration Study (OPPTS 870.7600)

In an *in vitro* dermal penetration study (MRID 47015601), HCO (purity 99%) was applied to twelve 0.64 cm<sup>2</sup> sections of male rat skin and twelve 0.64 cm<sup>2</sup> sections of human cadaver skin for eight hours at a rate of 30,000 µg/cm<sup>2</sup>. The skins specimens were contained in dual-chambered

diffusion cell assemblies. Receptor fluid samples were collected 0.5, 1, 2, 4, 6, 8, and 24 hours after the start of dosing. After eight hours of exposure, the skin specimens were washed with ethanol and tape stripped. All wash, receptor fluid samples, tape strip samples, and skin specimens were analyzed for HCO.

Penetration rates of HCO through rat skin were ~105 – 110-fold greater than through human skin during the initial *in vitro* eight hour exposure. The penetration rates declined approximately 18-fold for rat skin during the 16-hour post-exposure period, but was still approximately five-times greater than the rates reported for human skin. At the end of the study, the total absorbable dose was ~78% for rat skin and ~2% for human skin. While penetration rates through rat skin declined following removal of the test material, penetration rates through human skin were comparable during and after exposure. Total recovery of the test material for skin from both species and all time intervals was ≥89%.

Results from the oral and dermal subchronic toxicity studies (incidence of microscopic changes noted in the kidneys of male rats) suggest that dermal absorption is likely to be >20% based on comparison of the LOELs from the two studies ([oral LOEL/dermal LOEL] x 100). The *in vitro* dermal penetration study with rat and human skin indicated a high degree of penetration in rat skin (78% of the dose after an eight-hour exposure) while human skin was relatively impermeable (2% of the dose was absorbed during the same exposure period) to hydrogenated catmint oil. It should be noted that the application rate for the active ingredient in the dermal penetration study is similar to that determined from the 15% lotion's product performance study (approximately 80% of the product application rate).

#### B. Occupational and Residential Exposure

No occupational estimates are made in this assessment since HCO is to be used by individuals as an insect repellent that they apply directly to their own skin. Non-occupational dermal exposure estimates were not determined because the subchronic dermal toxicity study did not demonstrate an endpoint for use in risk characterization, and the label indicates that advice from a physician or Poison Control Center should be sought when reactions to exposure from use of the products are suspected. Again, the directions for use on the two product labels indicated that application of the lotions to children's fingers and hands was to be avoided. Therefore, no exposure estimates were determined for incidental oral exposure.

#### V. RISK CHARACTERIZATION

Based on the absence of short- and intermediate-term toxicity endpoints and precautionary labeling to avoid the likelihood of incidental oral exposure for small children, no risk characterizations are needed in this assessment.

Linda Hollis/DC/USEPA/US  
04/20/2007 08:57 AM

To Thomas C McEntee  
<Thomas.C.McEntee@usa.dupont.com>  
cc Leonard Cole/DC/USEPA/US@EPA, Raderrio  
Wilkins/DC/USEPA/US@EPA, Shannon L Koerber  
<Shannon.L.Koerber@usa.dupont.com>,  
bcc  
Subject Re: EPA File Symbols 71654-ER, EG and EN; Refined Oil of  
Nepeta cataria; PRIA Date

Dear Mr. McEntee: Your message below to Mr. Raderrio Wilkins suggests that you are unwilling to renegotiate the due date for the above products to our requested date of March 2008. Rather, you state that December 21, 2007 is the date acceptable to you. When we met in our offices in March 5th 2007, your packages were still incomplete. As a result of our meeting I forwarded to you the message immediately below: We are unable to accommodate your request of a due date of December 21, 2007 and will need to renegotiate to the said date of March 2008. If you are still unwilling to renegotiate to this date then we most likely not be able to complete our reviews by the current date.

Dear Mr. McEntee:

Per our meeting of March 1, 2007 we discussed several administrative deficiencies with regard to your products which are as follows: Please provide:

1. An updated data matrix for all of your products as referenced above. The updated data matrix should list the Tier 1 data requirements for Non target fate and effects and indicate how you intend to satisfy each data requirement. Should the data requirement fall under the category of not applicable, please so state. You may fax these forms to Leonard Cole at 703-305-0118. The forms are needed immediately but will not prevent your data from entering into the first phases of scientific review.
2. As discussed, the Agency will need to renegotiate the due date for these products. The current due date is Nov. 17, 2007. We will need to renegotiate out 3 months due to time lost to correct 86-5 deficiencies. The proposed due date will be March 2008. Of course, there may be the chance that the Agency will complete its review prior to that due date. As indicated in our meeting, I will need for you to confirm, via email, that the proposed new due date is acceptable in order that we may commence with the paper work for renegotiation.
3. The risk manager who will be assigned to your submissions is Mr. Raderrio Wilkins. As discussed, I encourage you to communicate with Mr. Wilkins with regard to the status of your applications however, please refrain from contacting him until the end of next week to allow him the opportunity to process the application materials as he will not be in receipt of these materials until the end of this week.

I look forward to hearing from you with regard to the proposed due date and receiving your administrative materials.

Linda A. Hollis  
Chief, Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs (7511P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202  
hollis.linda@epa.gov  
(703) 308-8733 (phone)  
(703) 308-7026 (fax)

Linda Hollis/DC/USEPA/US  
04/05/2007 01:26 PM

To Thomas.C.McEntee@usa.dupont.com  
cc andersen.janet@epa.gov, wilkins.raderrio@epa.gov,  
cole.leonard@epa.gov, wilkins.raderrio@epa.gov,  
fuentes.clara@epa.gov  
bcc

Subject Catnip Oil Products - The Tech and 2 ep's - Request to  
Renegotiate

Mr. McEntee: I am writing to you in response to your email to Mr. Raderrio Wilkins of my staff in which you agree to renegotiate the due date for your three pending products from Nov. 17, 2007 to December 21, 2007. The due date of December 21, 2007 is proposed by you based on the fact that you are in disagreement that BPPD will need to negotiate out 3 months from the original due date as communicated to you by me in our meeting of March 1, 2008. We are requesting 3 months of extended time because our records show that the 86-5 deficiencies in addition to deficiencies found during the BPPD preliminary screening and communicated to you in our meeting of March 1st and subsequent email from me to you on March 5th have taken that amount of time for completion. If you recall that during our meeting of March 1st, your submission packages were still deficient. During this meeting and in my follow up email to you where I again described the information necessary to make your packages complete, I stated that the proposed due date will be March 2008 and that there may be the chance that the Agency will complete's it's review prior to that due date. Therefore, our request is to renegotiate the due dates for the above products to March 31, 2008 and I will need for you to confirm, via email, that the proposed new due date is acceptable in order that we may commence with the paper work for renegotiation.

An additional new development that may potentially affect the due date is your most recent submission of documents per 1303 which are not 86-5 compliant. We will need to communicate those deficiencies to you (if they have not been already) and allow you the time to correct them. Time added to correct 86-5 deficiencies can have an impact on the PRIA due date.

I apologize if you do not fully understand our process however, it is imperative that we are afforded the time required for each phase of the pria review process so that we are better able to make our regulatory decisions by the dates provided.

I look forward to hearing from you so that we can move this forward.

P.S. As discussed with you in our March 1st meeting, please include or carbon copy me, Linda Hollis, in your communications to John Carley relative to information that you will be submitting.

Linda A. Hollis  
Chief, Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs (7511P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202  
hollis.linda@epa.gov  
(703) 308-8733 (phone)  
(703) 308-7026 (fax)



Thomas C McEntee  
<Thomas.C.McEntee@usa.dupont.com>

03/29/2007 12:29 PM

To Raderrio Wilkins/DC/USEPA/US@EPA

cc Leonard Cole/DC/USEPA/US@EPA, Linda Hollis/DC/USEPA/US@EPA, Shannon L Koerber  
<Shannon.L.Koerber@usa.dupont.com>

bcc

Subject Re: EPA File Symbols 71654-ER, EG and EN; Refined Oil of Nepeta cataria; PRIA Date

Mr. Raderrio Wilkins,

This is to confirm that I have discussed the subject of negotiated PRIA decision date with our management. Because of the time it took to resolve the 86-5 defects, we are agreeable to a PRIA date of December 21, 2007 for 71654-EN and ER. The 71654-EG can be extended although I would expect EPA to reach the same decision as is reached for 71654-ER.

EPA file symbols 71654-EN and 71654-ER were submitted Nov. 1, 2007 and the PRIA fee paid on Nov. 11. Because the confidential appendices were incorrectly paginated per 86-5 there was a delay until mid-December.

You mentioned the front-end screen and a gap associated with the screen. I lack insight into this activity and I'm unable to understand the justification for requesting a three month extension (until March 2008).

Should there be issues with the studies that have been submitted for review, there could be a basis to request an extension in order to respond to the issues. Presently, with the studies in primary review, it is difficult to appreciate that BPPD will not be in a position to make a decision on these applications by December 2007.

As discussed in the March 1, 2007 meeting with Ms. Linda Hollis, Roger Gardner, Russell Jones and Leonard Cole, the goal is to be able to bring this product to market for the US 2008 summer season. Obtaining the registration in March gives insufficient lead time to address the practical aspects of commercial agreement, supply, state registrations, advertising, logistics and etc. While extending a 12 month process to 15 months is not a large percentage increase, it does have a critical effect on the commercial timing with significant consequences to our business interests. Therefore, I respectfully request that we work together to secure a December 2007 approval.

Thank you for your assistance with our applications for registration.

Tom McEntee  
302 695 6856  
978 335 8055 CELL

Hollis.Linda@epam  
ail.epa.gov

03/05/2007 10:49  
AM

To  
Thomas C McEntee/AE/DuPont@DuPont  
cc  
wilkins.raderrio@epa.gov,  
cole.leonard@epa.gov

Subject  
Re: EPA File Symbols 71654-ER, EG

Linda Hollis/DC/USEPA/US  
03/05/2007 10:47 AM

To Thomas C McEntee  
<Thomas.C.McEntee@usa.dupont.com>  
cc wilkins.raderrio@epa.gov, cole.leonard@epa.gov  
bcc  
Subject Re: EPA File Symbols 71654-ER, EG and EN; Refined Oil of  
Nepeta cataria

Dear Mr. McEntee:

Per our meeting of March 1, 2007 we discussed several administrative deficiencies with regard to your products which are as follows: Please provide:

1. An updated data matrix for all of your products as referenced above. The updated data matrix should list the Tier 1 data requirements for Non target fate and effects and indicate how you intend to satisfy each data requirement. Should the data requirement fall under the category of not applicable, please so state. You may fax these forms to Leonard Cole at 703-305-0118. The forms are needed immediately but will not prevent your data from entering into the first phases of scientific review.

2. As discussed, the Agency will need to renegotiate the due date for these products. The current due date is Nov. 17, 2007. We will need to renegotiate out 3 months due to time lost to correct 86-5 deficiencies. The proposed due date will be March 2008. Of course, there may be the chance that the Agency will complete its review prior to that due date. As indicated in our meeting, I will need for you to confirm, via email, that the proposed new due date is acceptable in order that we may commence with the paper work for renegotiation.

*→ Linda  
sent request  
an email  
offer renegotiate*

3. The risk manager who will be assigned to your submissions is Mr. Raderrio Wilkins. As discussed, I encourage you to communicate with Mr. Wilkins with regard to the status of your applications however, please refrain from contacting him until the end of next week to allow him the opportunity to process the application materials as he will not be in receipt of these materials until the end of this week.

I look forward to hearing from you with regard to the proposed due date and receiving your administrative materials.

Linda A. Hollis  
Chief, Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs (7511P).  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202  
hollis.linda@epa.gov  
(703) 308-8733 (phone)  
(703) 308-7026 (fax)  
Visit <http://www.epa.gov/pesticides>

*The original tech  
data got mislabeled  
so general had to  
order them back*

Thomas C McEntee <Thomas.C.McEntee@usa.dupont.com>



Thomas C McEntee  
<Thomas.C.McEntee@usa.d  
upont.com>  
02/28/2007 11:01 AM

To Leonard Cole/DC/USEPA/US@EPA, Linda  
Hollis/DC/USEPA/US@EPA  
cc

Confirm Meeting - Thursday March 1, 2007 10:30 am EPA

*Assigned to R. Wilkins 3/13/07*

and EN; Refined Oil of Nepeta  
cataria

Dear Mr. McEntee:

Per our meeting of March 1, 2007 we discussed several administrative deficiencies with regard to your products which are as follows: Please provide:

1. An updated data matrix for all of your products as referenced above. The updated data matrix should list the Tier 1 data requirements for Non target fate and effects and indicate how you intend to satisfy each data requirement. Should the data requirement fall under the category of not applicable, please so state. You may fax these forms to Leonard Cole at 703-305-0118. The forms are needed immediately but will not prevent your data from entering into the first phases of scientific review.
2. As discussed, the Agency will need to renegotiate the due date for these products. The current due date is Nov. 17, 2007. We will need to renegotiate out 3 months due to time lost to correct 86-5 deficiencies. The proposed due date will be March 2008. Of course, there may be the chance that the Agency will complete's it's review prior to that due date. As indicated in our meeting, I will need for you to confirm, via email, that the proposed new due date is acceptable in order that we may commence with the paper work for renegotiation.
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I look forward to hearing from you with regard to the proposed due date and receiving your administrative materials.

Linda A. Hollis  
Chief, Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs (7511P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202  
hollis.linda@epa.gov  
(703) 308-8733 (phone)  
(703) 308-7026 (fax)  
Visit <http://www.epa.gov/pesticides>

Thomas C McEntee  
<Thomas.C.McEnte  
e@usa.dupont.com  
>

02/28/2007 11:01  
AM

Leonard Cole/DC/USEPA/US@EPA,  
Linda Hollis/DC/USEPA/US@EPA

To

cc

Subject

Confirm Meeting - Thursday March  
1, 2007 10:30 am EPA File  
Symbols 71654-EG and RE; Refined  
Oil of Nepeta cataria lotion

Confirm Meeting - Thursday March 1, 2007 10:30 am- EPA Potomac Yard  
Refined Oil of Nepeta cataria  
EPA File Symbols 71654-EG (7%Lotion) [23]  
ER(15%Lotion) [21]  
EN (Technical & manufacturing use) [20]

Mr. Leonard Cole and Ms. Linda Hollis,

This is to confirm the subject meeting. Notes from previous meetings are  
attached for your reference.

Please let me know if there will be anyone else in attendance besides  
yourselves.

(See attached file: 20060405 Meeting Notes.doc) (See attached file:  
20051207  
Meeting Notes.doc) (See attached file: March 17 2005 Meeting Intent  
Talking  
points.doc) (See attached file: EPA DuPont Dec 14 2004.doc)

Tom McEntee  
302 695 6856  
978 335 8055 CELL

Cole.Leonard@epam  
ail.epa.gov

To

02/23/2007 09:08

Thomas C McEntee/AE/DuPont@DuPont

AM

cc

David L

Hallahan/AE/DuPont@DuPont,

Koerber/AE/DuPont@DuPont,

Shannon L

Yesenia M Pelaez/AE/DuPont@DuPont

Subject

Re: EPA File Symbols 71654-EG and  
RE; Refined Oil of Nepeta cataria  
lotion; Ref: telephone Feb 21  
2007

Thanks Tom. This is a non-issue. I apologize for creating a stir.  
After carefully reviewing things and adding thought, I realized that  
this is a non-food use, and you have provided CAS Reg. Numbers for the  
inerts. We may have some other minor issues. I'll be in touch with you  
very soon. I appreciate your patience and understanding.

Leonard Cole

Thomas C McEntee  
<Thomas.C.McEnte  
e@usa.dupont.com  
>

02/22/2007 02:06  
PM

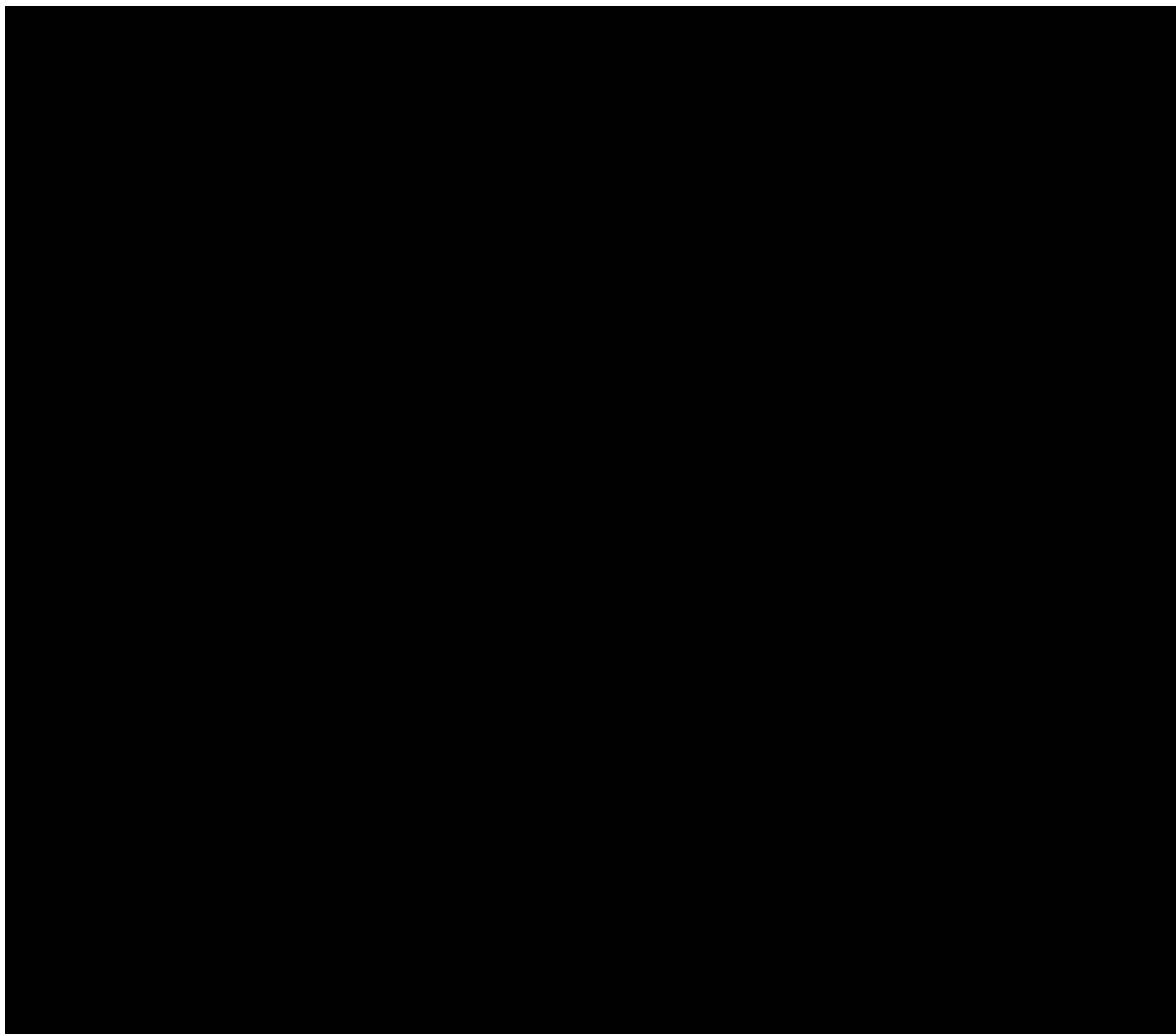
To  
Leonard Cole/DC/USEPA/US@EPA  
cc

Shannon L Koerber  
<Shannon.L.Koerber@usa.dupont.com  
>, Yesenia M Pelaez  
<Yesenia.M.Pelaez@usa.dupont.com>  
, David L Hallahan  
<David.L.Hallahan@USA.dupont.com>

Subject  
EPA File Symbols 71654-EG and RE;  
Refined Oil of Nepeta cataria  
lotion; Ref: telephone Feb 21  
2007

Mr. Leonard Cole

Thank you for your telephone call regarding the subject product and details regarding four of the inerts in the formulation. Please refer to the bookmarked attachments for further documentation of the four ingredients discussed yesterday.



Sincerely and thanks for your attention to our applications.

Tom McEntee  
302 695 6856  
978 335 8066 CELL

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transfers of data to third parties.

Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

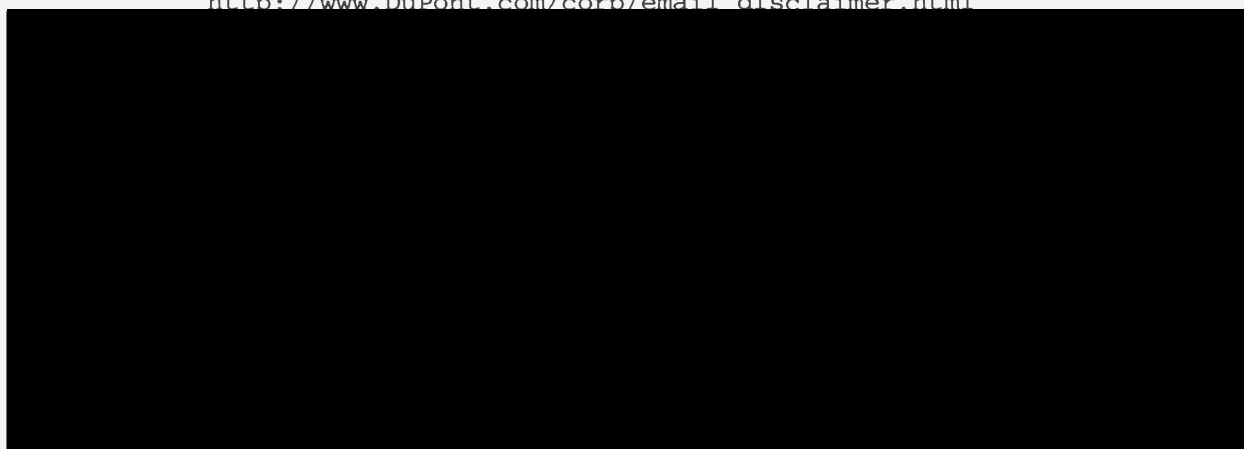
[http://www.DuPont.com/corp/email\\_disclaimer.html](http://www.DuPont.com/corp/email_disclaimer.html)



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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean




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 20060405 Meeting Notes.doc  20051207 Meeting Notes.doc  March 17 2005 Meeting Intent Talking points.doc

 EPA DuPont Dec 14 2004.doc 

 20070222 Inerts Complete list.pdf 



AM

February 4, 2007

Diana Hudson,

Thank you for the e-mail and attached letter.

However, the attachement does not include the bibiliography with MRID numbers, so I cannot cross-reference the studies which you found to have deficiencies.

Please forward the MRID numbers.

Sincerely,

Tom McEntee  
302 695 6856

Hudson.Diana@epam

ail.epa.gov

To

11/21/2006 08:12

Thomas C McEntee/AE/DuPont@DuPont

AM

cc

Subject

Refined Oil of Nepeta Cataria -

86-5 Failure; Reg./File Symbol

71654-EN; 75-day due date is

February 4, 2007

Thomas C. McEntec:

Please see attached file regarding the above registration. If you have any questions or problems with the pdf. file, please call.

Thank you,  
Diana Hudson  
(703) 308-8713

(See attached file: 71654-EN 86-5 failure.pdf)

(See attached file: 71654-EN 86-5 failure.pdf)

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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

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(See attached file: 71654-EN 86-5 failure.pdf) (See attached file: 71754-EN MRIDs.pdf) (See attached file: 71654-EN 86-5 failure.pdf)

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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

[http://www.DuPont.com/corp/email\\_disclaimer.html](http://www.DuPont.com/corp/email_disclaimer.html)

20061130 HCO Technical Transmittal Refected Studies.doc 20061130 Efficacy Fly Maine Reject 46797423 pages 81 and 82 Only.pdf

20061130 In vitro Reject page 2 MRID 46977414.pdf 71754-EN MRIDs.pdf 71654-EN 86-5 failure.pdf

# BPPD SCREEN PACKAGE

BPPD FRONT END: BPB/MPB: Act Team Leader: L. Cole

Pria Code/Action Code: B60 Team/RAL: \_\_\_\_\_

Product Name: Refined Oil of Nepeta cataria

EPA ID No.: 71654-EN / ER child

Active Ingredient(s): Refined Oil of Nepeta cataria (catnip oil)

\_\_\_\_\_ Food ☒ New Submission

☒ Non Food \_\_\_\_\_ Resubmission

Date In BPPD: 1/14/07

Date To Screen: 1/19/07

Date Expected From Screen: (10 days from date in): 1/30/07 WA# 06-68

Nasrin Begum: Henry Spencer Act. Hours 3 1/2 Return to BPPD: 1/24/07

Received Date from Contactor: 1/24/07 FR

## SCREEN PACKAGE NOTES:

Pre- Reg Meetings attached? \_\_\_\_\_ Yes ☒ No

Submission complies with all applicable areas of checklists? Indicate in detail on checklists forms when returned.

Additional Comments per Team Leader or Screener:

## SCREEN STATUS

Administrative: \_\_\_\_\_ Pass Fail

Scientific: Pass \_\_\_\_\_ Fail

# MEMORANDUM

DATE: 01/021/07

TO: PM 92, Regulatory Manager

FROM: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted in OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission  
☐ partially accepted submission  
☐ rejected submission

Administrative

Materials

$$EN = TECH$$

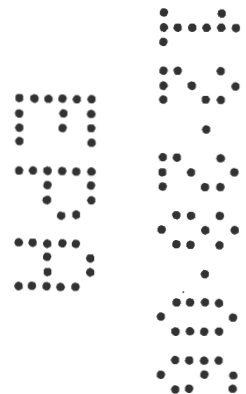
DATE: December 28, 2006

TO: Teresa Downs  
ITRMD, Rm. S6922

FROM: Diana Hudson  
Biopesticides and Pollution Prevention Division  
Office #: 308-8713

RE: Request for 86-5 Screening of Corrected Submission;  
EPA Reg. #/File Symbol: 71654-EN

The attached submission has been corrected for all 86-5 deficiencies and is being returned to you for 86-5 screening (Studies 14 & 23). All pages have been inserted and the EPA Transmittal letter along with the BPPD 86-5 Deficiency letter to the registrant is attached.



# MEMORANDUM

DATE: 12/15/06

TO: BPPD (91), Regulatory Manager

FROM: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted in OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:

- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission



**Thomas C McEntee**  
<Thomas.C.McEntee@usa.dupont.com>

11/30/2006 10:06 AM

To Diana Hudson/DC/USEPA/US@EPA

cc

bcc

Subject Re: Refined Oil of Nepeta Cataria - 86-5 Failure; Reg./File  
Symbol 71654-EN Confirmation of FAX

(See attached file: 20061130 HCO Technical Transmittal Rejected Studies.doc) (See attached file: 20061130 Efficacy Fly Maine Reject 46797423 pages 81 and 82 Only.pdf) (See attached file: 20061130 In vitro Reject page 2 MRID 46977414.pdf)

Ms. Diana Hudson,

This e-mail is to confirm that I have FAXed the above 4 pages in partial response the the rejected studies. The remiander will be sent by courier and should be received befor Dec. 8.

Thank you for your assistance.

Tom McEntee  
320 695 6856

Hudson.Diana@epam  
ail.epa.gov

11/21/2006 05:03  
PM

To  
Thomas C McEntee/AE/DuPont@DuPont  
cc

Subject  
Re: Refined Oil of Nepeta Cataria -  
86-5 Failure; Reg./File Symbol  
71654-EN; 75-day due date is  
February 4, 2007

Mr. McEntee, I'm so sorry for not including the list of MRIDs. Please see attached file.

Thank you,  
Diana

(See attached file: 71754-EN MRIDs.pdf)

Thomas C McEntee  
<Thomas.C.McEntee@usa.dupont.com>  
Sent by:  
Thomas.C.McEntee@usa.dupont.com

11/21/2006 10:28

To  
Diana Hudson/DC/USEPA/US@EPA  
cc

Subject  
Re: Refined Oil of Nepeta Cataria  
- 86-5 Failure; Reg./File Symbol  
71654-EN; 75-day due date is



Diana Hudson/DC/USEPA/US

11/21/2006 08:11 AM

To thomas.c.mcentee@usa.dupont.com

cc

bcc

Subject Refined Oil of Nepeta Cataria - 86-5 Failure; Reg./File  
Symbol 71654-EN; 75-day due date is February 4, 2007

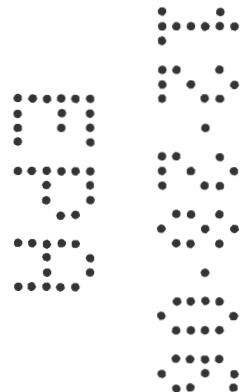
Thomas C. McEntee:

Please see attached file regarding the above registration. If you have any questions or problems with the pdf. file, please call.

Thank you,  
Diana Hudson  
(703) 308-8713



71654-EN 86-5 failure.pdf





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

November 21, 2006

Thomas C. McEntee  
Product Registration Manager  
DuPont Chemical Solutions Enterprise  
P.O. Box 80402  
Wilmington, DE 19880-0402

**RE: Refined Oil of Nepeta Cataria**  
**EPA Reg.#/File Symbol: 71654-EN**  
**Application dated: 10/18/2006**  
**Notification of Non-compliance with Pesticide Registration Notice 86-5**

Email sent date: 11/21/06  
Email address: [thomas.c.mcentee@usa.dupont.com](mailto:thomas.c.mcentee@usa.dupont.com)

Dear Mr. McEntee:

The Biopesticides and Pollution Prevention Division (BPPD) have received your submission to register the subject product. All or some of the data were rejected by our Document Processing Unit because they were not submitted as directed in PR Notice 86-5 and should be reformatted and resubmitted to the Document Processing Unit. A copy of PR Notice 86-5 can be found at our website at: [http://www.epa.gov/opppmsd1/PR\\_Notices/pr86-5.html](http://www.epa.gov/opppmsd1/PR_Notices/pr86-5.html) should you need assistance in making the necessary changes.

If you still want to register this product, the application will be kept open for a period of 75 days to give you an opportunity to respond to this memorandum. If you find that you need more time you must request an extension for a reasonable stated period of time. Extension requests must be made immediately to me at (703) 308-8713.

If you do not comply with this procedure by not responding to this letter or requesting an extension of time to resubmit the information, the Agency may administratively withdraw your application from further consideration under the provisions of PR Notice 75-4 of August 27, 1975. Once this is done, you will have to submit completely new application should you wish to pursue the registration of your product after the application has been withdrawn.

The changes and/or corrections required by you are outlined in the attached EPA Transmittal Letter. You must contact me by telephone at the number above or by email at [HUDSON.DIANA@EPA.GOV](mailto:HUDSON.DIANA@EPA.GOV) and indicate that you will submit the corrected pages via facsimile to (703) 305-0118. Once you have faxed the corrected pages, please follow up with an email to me indicating that you have done so.

If the changes are excessive, you may wish to fed-ex or courier the documents to our offices or contact me to arrange to come in to our offices to make the necessary changes. Once all changes have been made, your submission will be forwarded to our Document Processing Unit for PR Notice 86-5 Screening.

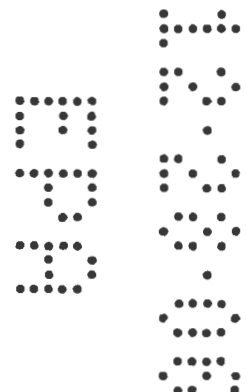
Should you have additional questions regarding this matter, please feel free to call me.

Sincerely,

*Diana Hudson*

Diana Hudson  
Biopesticides and Pollution Prevention  
Division (7511P)


Enclosure





**Diana Hudson/DC/USEPA/US**

11/21/2006 01:31 PM

To Thomas C McEntee  
<Thomas.C.McEntee@usa.dupont.com>  
cc  
bcc  
Subject Re: Refined Oil of Nepeta Cataria - 86-5 Failure; Reg./File  
Symbol 71654-EN; 75-day due date is February 4, 2007 

Mr. McEntee, I'm so sorry for not including the list of MRIDs. Please see attached file.

Thank you,  
Diana



71754-EN MRIDs.pdf

Thomas C McEntee <Thomas.C.McEntee@usa.dupont.com>



**Thomas C McEntee**  
<Thomas.C.McEntee@usa.d  
upont.com>

Sent by:  
Thomas.C.McEntee@usa.dup  
ont.com

11/21/2006 10:28 AM

To Diana Hudson/DC/USEPA/US@EPA  
cc  
Subject Re: Refined Oil of Nepeta Cataria - 86-5 Failure; Reg./File  
Symbol 71654-EN; 75-day due date is February 4, 2007

Diana Hudson,

Thank you for the e-mail and attached letter.

However, the attachement does not include the bibiliography with MRID numbers, so I cannot cross-reference the studies which you found to have deficiencies.

Please forward the MRID numbers.

Sincerely,

Tom McEntee  
302 695 6856

Hudson.Diana@epam  
ail.epa.gov

11/21/2006 08:12  
AM

To  
Thomas C McEntee/AE/DuPont@DuPont  
cc

Subject  
Refined Oil of Nepeta Cataria -  
86-5 Failure; Reg./File Symbol  
71654-EN; 75-day due date is  
February 4, 2007

Thomas C. McEntec:

Please see attached file regarding the above registration. If you have any questions or problems with the pdf. file, please call.

Thank you,  
Diana Hudson  
(703) 308-8713

(See attached file: 71654-EN 86-5 failure.pdf)

(See attached file: 71654-EN 86-5 failure.pdf)

This communication is for use by the intended recipient and contains information that may be Privileged, confidential or copyrighted under applicable law. If you are not the intended recipient, you are hereby formally notified that any use, copying or distribution of this e-mail, in whole or in part, is strictly prohibited. Please notify the sender by return e-mail and delete this e-mail from your system. Unless explicitly

and conspicuously designated as "E-Contract Intended", this e-mail does not constitute a contract offer, a contract amendment, or an acceptance of a contract offer. This e-mail does not constitute a consent to the use of sender's contact information for direct marketing purposes or for transfers of data to third parties.

Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

[http://www.DuPont.com/corp/email\\_disclaimer.html](http://www.DuPont.com/corp/email_disclaimer.html)



71654-EN 86-5 failure.pdf



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

November 17, 2006

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

E.I. DUPONT DE NEMOURS AND COMPANY  
DUPONT CHEMICAL SOLUTIONS ENTERPRISE  
EXPERIMENTAL STATION (ESL402/3224C, PO Box 80402  
WILMINGTON, DE 19880-0402

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 01-NOV-06. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.

The rejected studies and their deficiencies are described below.

Rejected Study [14]:

- \* You failed to sign the statement of data confidentiality claims included in the study.
- \* A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40CFR160 is required for all studies (except rangefinding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

Studies [16] - [19] were all rejected for the following reasons/s:

- \* When data confidentiality is claimed under FIFRA Section 10 (d)(1)(A), (B), or (C),

all confidential information must be excised from the body of the study and placed in a Confidential Attachment. See pages 8 and 15 of PR Notice 86-5.

Rejected Study [21]:

\* When data confidentiality is claimed under FIFRA Section 10 (d)(1)(A), (B), or (C), all confidential information must be excised from the body of the study and placed in a Confidential Attachment. See pages 8 and 15 of PR Notice 86-5.

Rejected Study [23]:

\* Judging from the pagination of the study, pages 81 & 82 were omitted from the submitted copy.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

November 17, 2006

71634-EN  
(Tech)  
OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

E.I. DUPONT DE NEMOURS AND COMPANY  
DUPONT CHEMICAL SOLUTIONS ENTERPRISE  
EXPERIMENTAL STATION (ESL402/3224C, PO Box 80402  
WILMINGTON, DE 19880-0402

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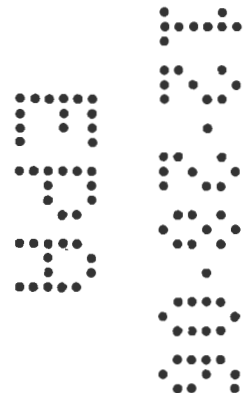
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\* Rejected Study [23]:

\* Judging from the pagination of the study, pages 81 & 82 were omitted from the submitted copy.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

November 17, 2006

71654-EN  
(Tech)  
OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

E.I. DUPONT DE NEMOURS AND COMPANY  
DUPONT CHEMICAL SOLUTIONS ENTERPRISE  
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WILMINGTON, DE 19880-0402

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Rejected Study [23]:

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Administrative

Materials

Kerry Leifer/DC/USEPA/US

11/09/2006 10:19 AM

To Leone Visse/DC/USEPA/US@EPA, Norman  
Spurling/DC/USEPA/US@EPA

cc

bcc

Subject EPA File Symbol 71654-EN

The Pesticide Chemical Code (PCC) 004801 has been assigned to the active ingredient **Nepeta cataria** oils.

If you have any questions, please feel free to contact me.

Kerry

Kerry Leifer, Team Leader  
Inert Ingredient Assessment Branch  
Registration Division (7505C)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460  
tel: (703) 308-8811  
fax: (703) 305-0599  
e-mail: leifer.kerry@epa.gov

Receipt for Section 3			
S:	800968	Resubmission:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Regulatory Type:	Product Registration - Section 3	Fee For Service:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Application Type:	New Registration	Billable:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Company:	71654 E.I. DUPONT DE NEMOURS AND COMPANY		V
Risk Manager:	Biologicals & Pollution Prevention Division, PM Team 91		
Product #:	71654-EH	Product Name:	Refined oil of Nepeta Cataria
Override#			
Me Too Section3:		Me Too Product Name:	
Application Date:	12-Oct-2006	OPP Rec'd Date:	01-Nov-2006
Front End Date:	02-Nov-2006	Risk Manager Send Date:	
FFS Due Date:		Negotiated Due Date:	
OPP Target Date:			
Fast Track:	<input type="checkbox"/>	New Ingredient:	<input type="checkbox"/>
Receipt Description:		Receipt Content	
Application for registration of new biochemical pesticide.		Study	
Form A:	<input type="checkbox"/>	Signature Date:	
Form B:	<input type="checkbox"/>	Signature Date:	

TRANSMITTAL DOCUMENT

**Attention:**

Document Processing Desk (REGFEE)  
Biopesticides and Pollution Prevention Division (BPPD)  
US Environmental Protection Agency  
Office of Pesticide Programs (7504P)  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

**NAME AND ADDRESS OF SUBMITTER**

E.I. du Pont de Nemours and Company  
DuPont Chemical Solutions Enterprise  
Experimental Station (ESL 402/3442A)  
P. O. Box 80402  
Wilmington, DE 19880-0402

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-

**Application for New Pesticide Registration Technical Ingredient**

**Refined oil of *Nepeta cataria*; EPA File Symbol 71654-**

Transmittal Date: **October 20, 2006**

**Transmittal Material:**

Volume 1	Administrative Materials	
	-Cover Letter	2 pages
	-Application for Pesticide Registration (EPA Form 8570-1)	1 page
	-Transmittal Document	4 pages
	-CSF (EPA Form 8570-4) October 12, 2006	1 pages
	- Data Matrix EPA form (8570-35)	6 pages
	-Certification Data Citation (8570-34)	1 page
	-Five copies of labeling	2 pages
	- Summary Data Requ. Biochemical Human Health Assessment	1 page
	- Copy Check No.3000068104 \$15,750.00 <b>PRIA B60</b>	1 check

Volume 2A Toxicology - Acute

- 46977401** **Acute Oral Toxicity – Rats – Up and Down** 870.1100; Finlay, Carol, Aug.9, 2005; E.I. duPont de Nemours and Company; Report No. 17740. 28 pages
- 46977402** **Acute Dermal Toxicity – Rats**; 870.1200; Finlay, Carol, July 19, 2005; E.I. duPont de Nemours and Company; Report No. 17550. 39 pages
- 46977403** **Acute Eye Irritation – Rabbits**; 870.2400; Finlay, Carol, July 11, 2005 E.I. duPont de Nemours and Company; Report No. 17533. 23 pages
- 46977404** **Acute Dermal Irritation – Rabbits**; 870.2500; Finlay, Carol, July 13, 2005, E.I. duPont de Nemours and Company; Report No. 17519. 23 pages
- 46977405** **Local Lymph Node Assay – Mice**; 870.2600; Hoban, Denise August 26, 2005, E.I. duPont de Nemours and Company; Report No. 17409. 41 pages
- 46977406** **Acute Inhalation Median Lethal Concentration (LC<sub>50</sub>) Rats** 870.1300 Oct. 10, 2005; DeLorme, M. P. ,E.I. duPont de Nemours and Company; Report No. 17408. 45 pages

Volume 2B Toxicology (Cont.)

- 46977407** **Subchronic Toxicity 90-day oral & Immunotox. 28-day**; (Part 1) 870.3100 and 870.3200 September 12, 2006; Munley, Susan, E.I. duPont de Nemours and Company; Report No. 174324 257 pages

Volume 2C Toxicology(Cont.)

- Subchronic Toxicity 90-day oral & Immunotox. 28-day** (Part 2); 870.3100 and 870.3200 September 12, 2006; Munley, Susan, E.I. duPont de Nemours and Company; Report No. 174324 308 pages

Volume 2D Toxicology (Cont.)

- 46977408** **Developmental Toxicity – Rats**; 870.3700 May 17, 2006 Mylchreest, Eve, E.I. duPont de Nemours and Company; Report No. 174343 161 pages

Volume 2E Toxicology (cont.)

- 46977409** **Acute Oral Neurotoxicity – Rats**; 870.6200 September 18, 2006; Munley, Susan M. , E.I. duPont de Nemours and Company; Report No. 19148 263 pages

Volume 2F Toxicology (Cont.)

- 46977410 Bacterial Reverse Mutation Test; 870.5100** August 10, 2005; 57 pages  
Ford, Lynn, E.I. duPont de Nemours and Company; Report No. 17471

Volume 2G Toxicology (Cont.)

- 46977411 In Vitro Mammalian Chromosome Aberration** 44 pages  
**Human Peripheral Lymphocytes; 870.5375** October 5, 2005;  
Gude, Ramedevi and Rao, Meena, RioReliance, DuPont No 17472

Volume 2H Toxicology(Cont.)

- 46977412 Mouse Bone Marrow Micronucleus; 870.5395** Feb. 28, 2006; 73 pages  
Donner, Maria; E.I. duPont de Nemours and Company; Report No. 18623

Volume 2I Toxicology (Cont.)

- 46977413 In Vitro Mammalian Cell Gene Mutation (L5178Y/TK+/-Mouse** 45 pages  
**Lymphoma Assay); 870.5300** November 10, 2005; Clark, Jane, J.,  
E.I. duPont de Nemours and Company; Report No. 17847.

Volume 2J Toxicology (Cont.)

- Reject (14) In Vitro Kinetics in Rat and Human Skin; OECD #428** Aug. 21, 2006; 51 pages  
Fasano, William, J.; E.I. duPont de Nemours and Company; Report No. 19930

Volume 2K Toxicology(Cont.)

- 46977415 Hydrogenated Catmint Oil: 28-day Repeated –Dose Dermal Toxicity** 345 pages  
**in Rats; 870.3200** August 29, 2006; Finlay, Carol; E.I. duPont de Nemours  
and Company; Report No. 17327

Volume 3A Chemistry

- Reject (16) Product Identity and Composition; 830.1100 Description of Starting** 14 pages  
**Materials, Production and Formulation Process 830.1200 and**  
**Discussion of the Formation of Impurities; 880.1400** October 12, 2006;  
Gonzalez, Yamaira et. al.; E.I. duPont de Nemours and Company.

Volume 3B Chemistry (Cont.)

- Reject (17) Five-Batch Analysis, Water Solubility Analysis, and Storage Stability** 47 pages  
**Analysis Of Hydrogenated Catnip Oil (HCO) Active Ingredient;**  
Guidelines 830.1700, 830.7840 830.6313, October 4, 2006; Exygen Research,  
Exygen Study Number: P0002395

Volume 3C Chemistry (Cont.)

- Reject (18)** **Enforcement Analytical Method;** 830.1800, October 12, 2006; Gonzalez, Yamaira I. and McEntee, Thomas C.; E.I. duPont de Nemours and Company 47 pages

Volume 3D Chemistry (Cont.)

- Reject (19)** **Certified Limits and Supplement to Preliminary Analysis;** 830.1750 October 12, 2006; Gonzalez, Yamaira, I. et. al. E.I. duPont de Nemours and Company. 14 pages

Volume 3E Chemistry (Cont.)

- 46977420** **Physical and Chemical Properties;** 830.6302, 830.6303, 830.6304, 830.6315, 830.7000, 830.7100, August 28, 2006; Case Consulting Laboratories Inc. , Exygen Research and E.I. duPont de Nemours and Company. 7 pages

Volume 3F Chemistry (Cont.)

- Reject (21)** **Hydrogenated Catnip: Determination of Boiling Point and Vapor Pressure for a Liquid TGA and Viscosity for Two Lotion Formulations;** Guideline 830.7220, 830.7950 830.7100 29 pages

Volume 3G Chemistry (Cont.)

- 46977422** **Summary of Physical and Chemical Characteristics of Technical Grade Active Ingredient;** October 12, 2006 7 pages

Volume 4A Efficacy

- Reject (23)** **Evaluation of the Efficacy of Personal Repellents Against Black Flies in Maine;** 810.3400 September 19, 2006; Insect and Control Research Inc. ICR Project Number 0306-313-0141. 140 pages

Volume 4B Efficacy (Cont.)

- 46977424** **Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Maine;** 810.3400; September 19, 2006; Insect and Control Research Inc. ICR Project No. 0306-313-0142. 104 pages

Volume 4C Efficacy (Cont.)

- 46977425** **Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Florida;** 810.3400; September 19, 2006; Insect and Control Research Inc. ICR Project Number 0306-313-0143. 104 pages



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

November 16, 2006

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

E.I. DUPONT DE NEMOURS AND COMPANY  
DUPONT CHEMICAL SOLUTIONS ENTERPRISE  
EXPERIMENTAL STATION (ESL402/3224C, PO Box 80402  
WILMINGTON, DE 19880-0402

Report of Analysis for Compliance with PR Notice 86-5

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The rejected studies and their deficiencies are described below.

Studies [07] - [09] were all rejected for the following reasons/s:

\* When data confidentiality is claimed under FIFRA Section 10 (d)(1)(A), (B), or (C), all confidential information must be excised from the body of the study and placed in a Confidential Attachment. See pages 8 and 15 of PR Notice 86-5.

Rejected Study [12]:

\* You must include one of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3

of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

\* When data confidentiality is claimed under FIFRA Section 10 (d)(1)(A), (B), or (C), all confidential information must be excised from the body of the study and placed in a Confidential Attachment. See pages 8 and 15 of PR Notice 86-5.

## NEW APPLICATIONS

DATE: NOV - 1 2006

FILE NUMBER: 71654 - E N

FEP (OPPIN ENTRY) L.V. NOV - 2 2006  
(Initial & date)

FILE ROOM: \_\_\_\_\_  
(Initial & date)

SIG: K.C. 11/7/06  
(Initial & date)

FILE ROOM: AC 11/8/06  
(Initial & date)

✓ ASSIGN TO PM 91 (NO DATA)

       JACKET TO SHELF (DATA)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

November 3, 2006

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-371861  
EPA File Symbol or Registration Number: 71654-EN  
Product Name: Refined Oil of Nepeta cataria  
EPA Receipt Date: 01-Nov-2006  
EPA Company Number: 71654  
Company Name: E.I. DUPONT DE NEMOURS AND COMPANY

Thomas McEntee  
E.I. DUPONT DE NEMOURS AND COMPANY  
DUPONT CHEMICAL SOLUTIONS ENTERPRISE  
EXPERIMENTAL STATION (ESL402/3224C, PO Box 80402  
WILMINGTON, DE 19880-0402

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B60

NEW AI;NON-FOOD USE;MICROBIAL/BIOCHEMICAL;

Please remit payment in the amount of: \$ 15,750 to:

By USPS:  
USEPA Washington Finance Center  
Pesticide Registration Service Fee  
PO Box 360277  
Pittsburgh, PA 15251

By Courier:

U.S. EPA Washington Finance Center  
Pesticide Registration Service Fee  
C/O Mellon Client Service Center  
500 Ross Street, Room 670  
Box 360277  
Pittsburgh, PA 15251-6277  
Attn: EPA Module Supervisor  
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at [www.epa.gov/pesticides/fees](http://www.epa.gov/pesticides/fees).

Please send Registration Service Fee Waiver requests to:

By USPS:

Document Processing Desk (WAIVER)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave NW  
Washington, DC 20460

By Courier:

Document Processing Desk (WAIVER)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 45 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8260.

Sincerely,

*Teresa Downs*

Front End Processing Staff  
Information Technology & Resources Management Division

# **FEE FOR SERVICE**

# Fee for Service

{800968N~

This package includes the following

- New Registration  
Amendment

✓ Studies? Fee Waiver?  
volpay % Reduction: \_\_\_\_

for Division

AD  
• BPPD  
RD

Risk Mgr. 91

Receipt No.

S-

800968

EPA File Symbol/Reg. No.

71654-EN

Pin-Punch Date:

11/1/2006

☐ This item is NOT subject to FFS action.

## Action Code:

Requested: B60

Granted: B60

Amount Due: \$ 15,750

## Parent/Child Decisions:

Parent = 71654-EN  
Child = 71654-ER

Reviewer: J. Ruff

Date: 11/2/06

Remarks:

# Receipt for Section 3

S: 800970

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 71654 E.I. DUPONT DE NEMOURS AND COMPANY V

Print Letter

Enter More Information

Tracking

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 71654-ER Product Name: REFINED OIL OF NEPETA CATARIA 15% LOTI

Overhead:

Me Too

Me Too

Section3:

Product Name:

Application Date: 18-Oct-2006

OPP Rec'd Date: 01-Nov-2006

Front End Date: 02-Nov-2006

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content

Study

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Application for Registration of new biochemical insect repellent formulation.  
IV

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

# Receipt for Section 3

S: 800968

Registration: ☒ Yes ☐ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 71654 E.J. DUPONT DE NEMOURS AND COMPANY V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 71654-EH Product Name:

OPTIONAL

Me Too Section3: Me Too Product Name:

Application Date: 12-Oct-2006 ic

OPP Rec'd Date: 01-Nov-2006 ic

Front End Date: 02-Nov-2006 ic

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Application for registration of new biochemical pesticide.  
lv

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study



DuPont Chemical Solutions Enterprise

October 18, 2006

Dr. Russell Jones  
Biopesticides and Pollution Prevention Division (BPPD)  
US Environmental Protection Agency  
Office of Pesticide Programs (7504P)  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

Subject: New Pesticide Application for Registration Technical and Manufacturing-Use  
"Refined Oil of *Nepeta cataria*"  
EPA File Symbol : 71654-

This letter and its attachments comprise DuPont's application for registration of a new insect repellent technical grade of active ingredient and manufacturing-use concentrate. There is a companion application for an end-use product, **Refined Oil of *Nepeta cataria* 15% Lotion**, which is submitted at the same time.

These two applications are based on the technology discussed with you and your staff on December 14, 2004, March 17, 2005 and February 27, 2006. During those discussions the active ingredient was referred to as **HYDROGENATED CATMINT OIL**. The product name and active ingredient name have been changed to facilitate global recognition and acceptance. Please also note the equivalency of 'catmint' with 'catnip' throughout.

Besides the **Refined Oil of *Nepeta cataria* 15% Lotion**, a substantially similar end-use formulation which contains **7% Refined Oil of *Nepeta cataria***, will be submitted within several weeks.

In support of the application, the following administrative documents are included:

Application for Pesticide Registration (EPA Form 8570-1)  
Transmittal Document  
CSF (EPA Form 8570-4) October 12, 2006  
Data Matrix EPA form (8570-35)  
Certification Data Citation (8570-34)  
Five copies of labeling (2 pages each)  
Summary Data Requ. Biochemical Human Health Assessment  
Copy Check No. 3000068104 \$15,750.00 PRIA B60

TRANSMITTAL DOCUMENT

**Attention:**

Document Processing Desk (REGFEE)  
Biopesticides and Pollution Prevention Division (BPPD)  
US Environmental Protection Agency  
Office of Pesticide Programs (7504P)  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

**NAME AND ADDRESS OF SUBMITTER**

E.I. du Pont de Nemours and Company  
DuPont Chemical Solutions Enterprise  
Experimental Station (ESL 402/3442A)  
P. O. Box 80402  
Wilmington, DE 19880-0402

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-

**Application for New Pesticide Registration Technical Ingredient**

**Refined oil of *Nepeta cataria*; EPA File Symbol 71654-**

Transmittal Date: **October 20, 2006**

**Transmittal Material:**

Volume 1	Administrative Materials	
	-Cover Letter	2 pages
	-Application for Pesticide Registration (EPA Form 8570-1)	1 page
	-Transmittal Document	4 pages
	-CSF (EPA Form 8570-4) October 12, 2006	1 pages
	- Data Matrix EPA form (8570-35)	6 pages
	-Certification Data Citation (8570-34)	1 page
	-Five copies of labeling	2 pages
	- Summary Data Requ. Biochemical Human Health Assessment	1 page
	- Copy Check No.3000068104 \$15,750.00 PRIA B60	1 check

Volume 2A Toxicology - Acute

**Acute Oral Toxicity – Rats – Up and Down** 870.1100; Finlay, Carol, 28 pages  
Aug.9, 2005; E.I. duPont de Nemours and Company; Report No. 17740.

**Acute Dermal Toxicity – Rats**; 870.1200; Finlay, Carol, July 19, 2005; 39 pages  
E.I. duPont de Nemours and Company; Report No. 17550.

**Acute Eye Irritation – Rabbits**; 870.2400; Finlay, Carol, July 11, 2005 23 pages  
E.I. duPont de Nemours and Company; Report No. 17533.

**Acute Dermal Irritation – Rabbits**; 870.2500; Finlay, Carol, 23 pages  
July 13, 2005, E.I. duPont de Nemours and Company; Report No. 17519.

**Local Lymph Node Assay – Mice**; 870.2600; Hoban, Denise 41 pages  
August 26, 2005, E.I. duPont de Nemours and Company; Report No. 17409.

**Acute Inhalation Median Lethal Concentration (LC<sub>50</sub>) Rats** 45 pages  
870.1300 Oct. 10, 2005; DeLorme, M. P. ,E.I. duPont de Nemours and Company;  
Report No. 17408.

Volume 2B Toxicology (Cont.)

**Subchronic Toxicity 90-day oral & Immunotox. 28-day; (Part 1)** 257 pages  
870.3100 and 870.3200 September 12, 2006; Munley, Susan,  
E.I. duPont de Nemours and Company; Report No. 174324

Volume 2C Toxicology(Cont.)

**Subchronic Toxicity 90-day oral & Immunotox. 28-day (Part 2);** 308 pages  
870.3100 and 870.3200 September 12, 2006; Munley, Susan,  
E.I. duPont de Nemours and Company; Report No. 174324

Volume 2D Toxicology (Cont.)

**Developmental Toxicity – Rats**; 870.3700 May 17, 2006 161 pages  
Mylchreest, Eve, E.I. duPont de Nemours and Company;  
Report No. 174343

Volume 2E Toxicology (cont.)

**Acute Oral Neurotoxicity – Rats**; 870.6200 September 18, 2006; Munley, 263 pages  
Susan M. , E.I. duPont de Nemours and Company; Report No. 19148

Volume 2F Toxicology (Cont.)

**Bacterial Reverse Mutation Test; 870.5100** August 10, 2005;  
Ford, Lynn, E.I. duPont de Nemours and Company; Report No. 17471

57 pages

Volume 2G Toxicology (Cont.)

**In Vitro Mammalian Chromosome Aberration  
Human Peripheral Lymphocytes; 870.5375** October 5, 2005;  
Gude, Ramedevi and Rao, Meena, RioReliance, DuPont No 17472

44 pages

Volume 2H Toxicology(Cont.)

**Mouse Bone Marrow Micronucleus; 870.5395** Feb. 28, 2006;  
Donner, Maria; E.I. duPont de Nemours and Company; Report No. 18623

73 pages

Volume 2I Toxicology (Cont.)

**In Vitro Mammalian Cell Gene Mutation (L5178Y/TK+/-Mouse  
Lymphoma Assay); 870.5300** November 10, 2005; Clark, Jane, J.,  
E.I. duPont de Nemours and Company; Report No. 17847.

45 pages

Volume 2J Toxicology (Cont.)

**In Vitro Kinetics in Rat and Human Skin; OECD #428** Aug. 21, 2006;  
Fasano, William, J.; E.I. duPont de Nemours and Company; Report No. 19930

51 pages

Volume 2K Toxicology(Cont.)

**Hydrogenated Catmint Oil: 28-day Repeated -Dose Dermal Toxicity  
in Rats; 870.3200** August 29, 2006; Finlay, Carol; E.I. duPont de Nemours  
and Company; Report No. 17327

345 pages

Volume 3A Chemistry

**Product Identity and Composition; 830.1100 Description of Starting  
Materials, Production and Formulation Process 830.1200 and  
Discussion of the Formation of Impurities; 880.1400** October 12, 2006;  
Gonzalez, Yamaira et. al.; E.I. duPont de Nemours and Company.

14 pages

Volume 3B Chemistry (Cont.)

**Five-Batch Analysis, Water Solubility Analysis, and Storage Stability  
Analysis Of Hydrogenated Catnip Oil (HCO) Active Ingredient;  
Guidelines 830.1700, 830.7840 830.6313,** October 4, 2006; Exygen Research,  
Exygen Study Number: P0002395

47 pages

Volume 3C Chemistry (Cont.)

**Enforcement Analytical Method;** 830.1800, October 12, 2006; Gonzalez, Yamaira I. and McEntee, Thomas C.; E.I. duPont de Nemours and Company 47 pages

Volume 3D Chemistry (Cont.)

**Certified Limits and Supplement to Preliminary Analysis;** 830.1750 14 pages  
October 12, 2006; Gonzalez, Yamaira, I. et. al. E.I. duPont de Nemours and Company.

Volume 3E Chemistry (Cont.)

**Physical and Chemical Properties;** 830.6302, 830.6303, 830.6304, 7 pages  
830.6315, 830.7000, 830.7100, August 28, 2006; Case Consulting Laboratories Inc., Exygen Research and E.I. duPont de Nemours and Company.

Volume 3F Chemistry (Cont.)

**Hydrogenated Catnip: Determination of Boiling Point and Vapor Pressure for a Liquid TGAI and Viscosity for Two Lotion Formulations;** 29 pages  
Guideline 830.7220, 830.7950 830.7100

Volume 3G Chemistry (Cont.)

**Summary of Physical and Chemical Characteristics of Technical Grade Active Ingredient;** October 12, 2006 7 pages

Volume 4A Efficacy

**Evaluation of the Efficacy of Personal Repellents Against Black Flies in Maine;** 810.3400 September 19, 2006; Insect and Control Research Inc. 140 pages  
ICR Project Number 0306-313-0141.

Volume 4B Efficacy (Cont.)

**Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Maine;** 810.3400; September 19, 2006; Insect and Control Research Inc. 104 pages  
ICR Project No. 0306-313-0142.

Volume 4C Efficacy (Cont.)

**Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Florida;** 810.3400; September 19, 2006; Insect and Control Research Inc. ICR Project 104 pages  
Number 0306-313-0143.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
1200 Pennsylvania Avenue, N.W.  
WASHINGTON, D.C. 20460

Form Approved OMB Nos. 2070-0060; 2070-0057;  
2070-0107; 2070-0122; 2070-0164

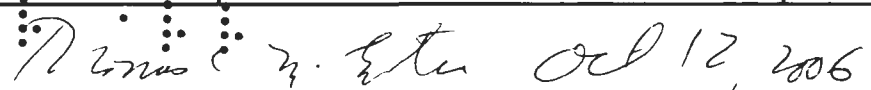
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DATA MATRIX

Date	October 12, 2006	EPA Reg No./File Symbol	71654	Page / of	3
Applicant's/Registrant's Name & Address		Product			
E. I. du Pont de Nemours and Company ESL 402/3224A P.O. Box 80402 Wilmington, DE 19880-0403		Refined oil of Nepeta cataria-Technical & Manufacturing Use Concentrate			

Ingredient Refined Oil of Nepeta cataria

					Submitter	Status	Note
					E.I du Pont de Nemours		Attached
					E.I du Pont de Nemours		Attached
					E.I du Pont de Nemours		Attached
					E.I du Pont de Nemours		Attached
					E.I du Pont de Nemours		Attached
					E.I du Pont de Nemours		Attached
					E.I du Pont de Nemours		Attached
					E.I du Pont de Nemours		Attached
					E.I du Pont de Nemours		Attached
					E.I du Pont de Nemours		Attached
					E.I du Pont de Nemours	Attached	Attached
					E.I du Pont de Nemours		Attached
					E.I du Pont de Nemours		Attached
					E.I du Pont de Nemours		Attached

Signature		Name and Title	Thomas C. McEntee, Product Registration Manager	Date	Oct 12, 2006
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401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 10/12/2006	EPA Reg No./File Symbol 71654-	Page 2 of 3
Applicant's/Registrant's Name & Address E.I. duPont de Nemours and Company, P.O. Box 80402 Wilmington, DE 19880-0402	Product Refined Oil of Nepeta cataria	

Ingredient Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			E.I. duPont de Nemours and Company	Attached	
			E.I. duPont de Nemours and Company	Attached	
			E.I. duPont de Nemours and Company	Attached	
			E.I. duPont de Nemours and Company	Attached	
			E.I. duPont de Nemours and Company	Attached	
			E.I. duPont de Nemours and Company	Attached	
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			E.I. duPont de Nemours and Company	Attached	
			E.I. duPont de Nemours and Company	Attached	
			E.I. duPont de Nemours and Company	Attached	
			E.I. duPont de Nemours and Company	Attached	

Signature <i>Thomas C. McEntee</i>	Name and Title Thomas C. McEntee Product Registration Manager	Date 10/12/2006
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 10/12/2006			EPA Reg No./File Symbol 71654-		Page 3 of 3
Applicant's/Registrant's Name & Address E.I. duPont de Nemours and Company, P.O. Box 80402 Wilmington, DE 19880-0402			Product Refined Oil of Nepeta cataria		
Ingredient Refined Oil of Nepeta cataria					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			E.I. duPont de Nemours and Company	Attached	
			E.I. duPont de Nemours and Company	Attached	
			E.I. duPont de Nemours and Company	Attached	
			E.I. duPont de Nemours and Company	Attached	
			E.I. duPont de Nemours and Company	Attached	
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			E.I. duPont de Nemours and Company	Attached	
			E.I. duPont de Nemours and Company	Attached	
			E.I. duPont de Nemours and Company	Attached	
			E.I. duPont de Nemours and Company	Attached	
Signature <i>Thomas C. McEntee</i> Oct 12, 2006			Name and Title Thomas C. McEntee		Date 10/12/2006



United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 71654- <i>EN</i>	2. EPA Product Manager	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Refined Oil of Nepeta cataria	PM# <i>91</i>	
5. Name and Address of Applicant (Include ZIP Code) E.I. du Pont de Nemours and Company Dupont Chemical Solutions Enterprise, P. O. Box 80402 Experimental Station (ESL402/3224C) Wilmington, DE 19880-0402  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application for registration of new biochemical pesticide

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled <input type="checkbox"/> Other _____					

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Thomas C. McEntee	Title Product Registration Manager	Telephone No. (Include Area Code) 302 695 6856
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment, both under applicable law.		6. Date Application Received (Stamped)     247
2. Signature <i>Thomas C. McEntee</i>	3. Title Product Registration Manager	
4. Typed Name Thomas C. McEntee	5. Date October 12, 2006	



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number E. I. duPont de Nemours and Company; P. O. Box 80402 Wilmington, DE 19880 (302) 695 6856	EPA Registration Number/File Symbol 71654-
Active Ingredient(s) and/or representative test compound(s) Refined Oil of Nepeta cataria	Date
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) For Manufacturing Insect Repellent Formulas for Human Use	Product Name Refined Oil of Nepeta cataria

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Thomas C. McEntee</i>	Date Oct. 12, 2006	Typed or Printed Name and Title Thomas C. McEntee; Product Registration Manager
---------------------------------------	-----------------------	--

## Refined Oil of *Nepeta cataria*

Insect Repellent Technical and Manufacturing Use Concentrate

### ACTIVE INGREDIENT:

Refined Oil of *Nepeta cataria*.....100.0%

EPA Reg. No. 71654-

EPA Est. No. XXXXX-YY-ZZZ

**KEEP OUT OF REACH OF CHILDREN**

### CAUTION

See [Back Panel][Side Panel][Product Leaflet] for Additional Precautions

Manufactured By:  
E.I. du Pont de Nemours and Company  
PO Box 80402  
Wilmington, DE 19880-0402

Net Contents: \_\_\_\_\_

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed. Avoid Contact with Skin, Eyes or Clothing. Causes Eye Irritation. Do not get in eyes, on skin or clothing.

#### PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame.

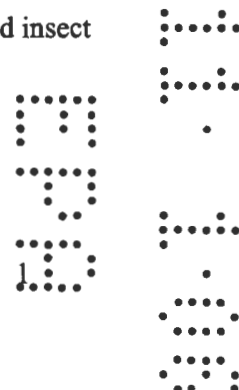
#### ENVIRONMENTAL HAZARDS

Keep out of lakes, ponds or streams.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Refer to technical data sheet for instructions on the formulation of end-use EPA-registered insect repellent formulations.



## FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

### If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

### If on Skin or Clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for further treatment advice.

### If Swallowed:

- Call Poison Control Center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

### If Inhaled

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call Poison Control Center or doctor for further treatment advice.

**Emergency Contact Number: 1-800-3637(US & Canada) or 1-302-774-1139 (all other areas).**

For 24-hour transportation emergency information on this product, call Chemtrec at 1-800-424-9300 (US Canada, Puerto Rico, & Virgin Islands); 1-703 527-3887 (all other areas)

**Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**Storage:** Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 130°F (54°C).

**Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Disposal:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Summary of data requirements for biochemical human health assessment  
 Refined oil of *Nepeta cataria* product  
 EPA Reg. No. 71654-

Guideline #	Haskell Lab #	Study
<i>Acute</i>		
870.1100	17740	Acute oral toxicity study in rats
870.1200	17550	Acute dermal toxicity study in rats
870.1300	17408	Inhalation LC50 study in rats
870.2400	17533	Acute eye irritation study in rabbits
870.2500	17519	Acute dermal irritation study in rabbits
870.2600	17409	Skin sensitization; local lymph node assay in mice
<i>Subchronic</i>		
870.3100	17324	90-Day oral (rat) – subchronic toxicity 90-day oral gavage study and immunotoxicity 28-day oral gavage study in rats
870.3250	17327	90-Day dermal (rat) – 28-day repeat-dose dermal toxicity study in rats Report refers to OPPTS 870.3200 (1998)
870.3465		90-day inhalation (rat) Not applicable based on low acute toxicity as demonstrated in Haskell Lab report#17408
<i>Developmental toxicity</i>		
870.3700	17343	Prenatal development – developmental toxicity study in rats
<i>Mutagenicity</i>		
870.5100	17471	Genotoxicity - bacterial reverse mutation study
870.5300	17847	Genotoxicity - <i>in vitro</i> mammalian cell gene mutation test
870.5395	18623	Tier II Genotoxicity – mouse bone marrow micronucleus test
870.5375	17472	Genotoxicity - <i>in vitro</i> mammalian chromosomal aberration study in human peripheral blood lymphocytes
<i>Special tests</i>		
880.3550	17324	Immunotoxicity - subchronic toxicity 90-day oral gavage study and immunotoxicity 28-day oral gavage study in rats (see Haskell report # 17324)
870.6200	19148	Neurotoxicity screening battery – acute oral neurotoxicity study in rats
	19930	In vitro dermal kinetics; rat and human

E. I. DUPONT DE NEMOURS & COMPANY  
DuPont Payment Services  
P. O. Box 80040  
Wilmington, DE 19880-0040

10/10/06

US GOVT  
US EPA WASHINGTON FINANCE CTR  
PESTICIDE REGISTRATION SVC FEED  
PO BOX 360277  
PITTSBURGH, PA 15251-6277

DOCUMENT NO.	INVOICE NO.	DATE	GROSS	DISCOUNT	NET
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TOTALS			\$15,750.00	0.00	\$15,750.00

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Attachment  
Check # 3000068104

THE FACE OF THIS CHECK IS PRINTED BLUE - THE BACK CONTAINS A SIMULATED WATERMARK



E. I. DUPONT DE NEMOURS & COMPANY  
DuPont Payment Services  
P. O. Box 80040  
Wilmington, DE 19880-0040

62-20  
311

No. 3000068104

PAY TO  
THE ORDER OF

US GOVT  
US EPA WASHINGTON FINANCE CTR  
PESTICIDE REGISTRATION SVC FEED  
PO BOX 360277  
PITTSBURGH, PA 15251-6277

10/10/06

Fifteen thousand seven hundred fifty and 00/100 Dollars

\*\*\*\*\*\$15,750.00

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NEW CASTLE, DE 19720

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US Environmental Protection Agency  
Office of Pesticide Programs (7504P)  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

**NAME AND ADDRESS OF SUBMITTER**

E.I. du Pont de Nemours and Company  
DuPont Chemical Solutions Enterprise  
Experimental Station (ESL 402/3442A)  
P. O. Box 80402  
Wilmington, DE 19880-0402

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-

**Application for New Pesticide Registration End-Use Product**

**Refined oil of *Nepeta cataria* 15% Lotion; EPA File Symbol 71654-**

Transmittal Date: **October 20, 2006**

**Transmittal Material:**

Volume 1     Administrative Materials

- Cover Letter	1 page
- Application for Pesticide Registration (EPA Form 8570-1)	1 page
- Transmittal Document	3 pages
- CSF (EPA Form 8570-4), October 19, 2006	1 pages
- Data Matrix EPA form (8570-35)	2 pages
- Certification Data Citation (8570-34)	1 page
- Five copies of labeling	4 pages
- Copy Check No. 3000068102	1 check

Volume 2A Toxicology - Acute

<b>46977301</b>	<b>Acute Oral Toxicity – Rats – Up and Down</b> 870.1100; August 31, 2006 Finlay, Carol; E.I. duPont de Nemours and Company; No. 20904	27 pages
<b>46977302</b>	<b>Acute Dermal Toxicity – Rats;</b> 870.1200 August 31, 2006 Finlay, Carol; E.I. duPont de Nemours and Company; No. 20889	34 pages
<b>46977303</b>	<b>Acute Eye Irritation – Rabbits;</b> 870.2400 September 29, 2006; Finlay, Carol; E.I. duPont de Nemours and Company; No. 20905	22 pages
<b>46977304</b>	<b>Acute Dermal Irritation – Rabbits;</b> 870.2500 August 29, 2006 Finlay, Carol; E.I. duPont de Nemours and Company; No. 20907	23 pages
<b>46977305</b>	<b>Local Lymph Node Assay – Mice;</b> 870.2600 September 18, 2006 Hoban, Denise; E.I. duPont de Nemours and Company; No. 20161	36 pages
<b>46977306</b>	<b>Acute Inhalation Toxicity - Waiver Request</b> 870.1300 October 13, 2006; Hallahan, D.L., Stadler, Judy and McEntee, T. C. E.I. duPont de Nemours and Company	7 pages

Volume 3A Chemistry

<b>Reject (07)</b>	<b>Product Identity and Composition;</b> 830.1100 <b>Description of Starting Materials, Production and Formulation Process;</b> 830.1200 <b>and Discussion of the Formation of Impurities</b> 880.1400; October 12, 2006; Gonzalez, Y. I. et. al; E.I. duPont de Nemours and Company.	9 pages
<b>Reject (08)</b>	<u>Volume 3B Chemistry (Cont.)</u>  <b>Enforcement Analytical Method for Formulations;</b> 830.1800, October 12, 2006, Gonzalez, Y. I., McEntee, T.C.; E.I. duPont de Nemours and Company and Exygen Research.	48 pages
<b>Reject (09)</b>	<u>Volume 3C Chemistry (Cont.)</u>  <b>Certified Limits Lotion Formulations CLI 1630802C and CLI 1630802D;</b> 830.1750; October 12, 2006; Gonzalez, Y. I., et. al; E.I. duPont de Nemours and Company.	7 pages
<b>46977310</b>	<u>Volume 3D Chemistry (Cont.)</u>  <b>Summary of Physical and Chemical Characteristics of Formulations</b> <b>CLI 1630802C and CLI 1630802D;</b> October 12, 2006; Gonzalez, Y. I. and McEntee, T. C., E.I. duPont de Nemours and Company and Exygen Research Series 830.	6 pages
<b>46977311</b>	<u>Volume 3E Chemistry (Cont.)</u> <b>Physical and Chemical Characteristics of 15wt.% Hydrogenated Catmint</b> <b>Oil Lotion: Physical State, Flammability and pH;</b> August 28, 2006; Sinning, D.J.; Case Consulting Laboratories Inc.	7 pages

**Reject (12)** Volume 3F Chemistry (Cont.)

**Characterization of Aged Hydrogenated Catnip Oil (HCO) Formulations** 40 pages  
OPPTS 830.7300 [Density] and 40 CFR 160.105 [Stability 830.6317];  
October 4, 2006; Kahler, T.W.; Exygen Research.

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DuPont Chemical Solutions Enterprise  
Experimental Station (ESL 402/3442A)  
P. O. Box 80402  
Wilmington, DE 19880-0402

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-

**Application for New Pesticide Registration Technical Ingredient**

**Refined oil of *Nepeta cataria*; EPA File Symbol 71654-**

Transmittal Date: **October 20, 2006**

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Volume 2A Toxicology - Acute

- 46977401** **Acute Oral Toxicity – Rats – Up and Down** 870.1100; Finlay, Carol, Aug.9, 2005; E.I. duPont de Nemours and Company; Report No. 17740. 28 pages
- 46977402** **Acute Dermal Toxicity – Rats**; 870.1200; Finlay, Carol, July 19, 2005; E.I. duPont de Nemours and Company; Report No. 17550. 39 pages
- 46977403** **Acute Eye Irritation – Rabbits**; 870.2400; Finlay, Carol, July 11, 2005 E.I. duPont de Nemours and Company; Report No. 17533. 23 pages
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- 46977405** **Local Lymph Node Assay – Mice**; 870.2600; Hoban, Denise August 26, 2005, E.I. duPont de Nemours and Company; Report No. 17409. 41 pages
- 46977406** **Acute Inhalation Median Lethal Concentration (LC<sub>50</sub>) Rats** 870.1300 Oct. 10, 2005; DeLorme, M. P. ,E.I. duPont de Nemours and Company; Report No. 17408. 45 pages

Volume 2B Toxicology (Cont.)

- 46977407** **Subchronic Toxicity 90-day oral & Immunotox. 28-day; (Part 1)** 870.3100 and 870.3200 September 12, 2006; Munley, Susan, E.I. duPont de Nemours and Company; Report No. 174324 257 pages

Volume 2C Toxicology(Cont.)

- Subchronic Toxicity 90-day oral & Immunotox. 28-day (Part 2);** 870.3100 and 870.3200 September 12, 2006; Munley, Susan, E.I. duPont de Nemours and Company; Report No. 174324 308 pages

Volume 2D Toxicology (Cont.)

- 46977408** **Developmental Toxicity – Rats**; 870.3700 May 17, 2006 Mylchreest, Eve, E.I. duPont de Nemours and Company; Report No. 174343 161 pages

Volume 2E Toxicology (cont.)

- 46977409** **Acute Oral Neurotoxicity – Rats**; 870.6200 September 18, 2006; Munley, Susan M. , E.I. duPont de Nemours and Company; Report No. 19148 263 pages

Volume 2F Toxicology (Cont.)

- 46977410 Bacterial Reverse Mutation Test; 870.5100** August 10, 2005; 57 pages  
Ford, Lynn, E.I. duPont de Nemours and Company; Report No. 17471

Volume 2G Toxicology (Cont.)

- 46977411 In Vitro Mammalian Chromosome Aberration** 44 pages  
**Human Peripheral Lymphocytes; 870.5375** October 5, 2005;  
Gude, Ramedevi and Rao, Meena, RioReliance, DuPont No 17472

Volume 2H Toxicology(Cont.)

- 46977412 Mouse Bone Marrow Micronucleus; 870.5395** Feb. 28, 2006; 73 pages  
Donner, Maria; E.I. duPont de Nemours and Company; Report No. 18623

Volume 2I Toxicology (Cont.)

- 46977413 In Vitro Mammalian Cell Gene Mutation (L5178Y/TK+/-Mouse** 45 pages  
**Lymphoma Assay); 870.5300** November 10, 2005; Clark, Jane, J.,  
E.I. duPont de Nemours and Company; Report No. 17847.

Volume 2J Toxicology (Cont.)

- Reject (14) In Vitro Kinetics in Rat and Human Skin; OECD #428** Aug. 21, 2006; 51 pages  
Fasano, William, J.; E.I. duPont de Nemours and Company; Report No. 19930

Volume 2K Toxicology(Cont.)

- 46977415 Hydrogenated Catmint Oil: 28-day Repeated –Dose Dermal Toxicity** 345 pages  
**in Rats; 870.3200** August 29, 2006; Finlay, Carol; E.I. duPont de Nemours  
and Company; Report No. 17327

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**Discussion of the Formation of Impurities; 880.1400** October 12, 2006;  
Gonzalez, Yamaira et. al.; E.I. duPont de Nemours and Company.

Volume 3B Chemistry (Cont.)

- Reject (17) Five-Batch Analysis, Water Solubility Analysis, and Storage Stability** 47 pages  
**Analysis Of Hydrogenated Catnip Oil (HCO) Active Ingredient;**  
Guidelines 830.1700, 830.7840 830.6313, October 4, 2006; Exygen Research,  
Exygen Study Number: P0002395

Volume 3C Chemistry (Cont.)

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Volume 3E Chemistry (Cont.)

- 46977420** **Physical and Chemical Properties;** 830.6302, 830.6303, 830.6304, 830.6315, 830.7000, 830.7100, August 28, 2006; Case Consulting Laboratories Inc., Exygen Research and E.I. duPont de Nemours and Company. 7 pages

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- Reject (21)** **Hydrogenated Catnip: Determination of Boiling Point and Vapor Pressure for a Liquid TGAI and Viscosity for Two Lotion Formulations;** Guideline 830.7220, 830.7950 830.7100 29 pages

Volume 3G Chemistry (Cont.)

- 46977422** **Summary of Physical and Chemical Characteristics of Technical Grade Active Ingredient;** October 12, 2006 7 pages

Volume 4A Efficacy

- Reject (23)** **Evaluation of the Efficacy of Personal Repellents Against Black Flies in Maine;** 810.3400 September 19, 2006; Insect and Control Research Inc. ICR Project Number 0306-313-0141. 140 pages

Volume 4B Efficacy (Cont.)

- 46977424** **Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Maine;** 810.3400; September 19, 2006; Insect and Control Research Inc. ICR Project No. 0306-313-0142. 104 pages

Volume 4C Efficacy (Cont.)

- 46977425** **Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Florida;** 810.3400; September 19, 2006; Insect and Control Research Inc. ICR Project Number 0306-313-0143. 104 pages

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Office of Pesticide Programs (7504P)  
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**NAME AND ADDRESS OF SUBMITTER**

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DuPont Chemical Solutions Enterprise  
Experimental Station (ESL 402/3442A)  
P. O. Box 80402  
Wilmington, DE 19880-0402

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-

**Application for New Pesticide Registration Technical Ingredient**

**Refined oil of *Nepeta cataria*; EPA File Symbol 71654-**

Transmittal Date: **October 20, 2006**

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DuPont Chemical Solutions Enterprise

October 18, 2006

Dr. Russell Jones  
Biopesticides and Pollution Prevention Division (BPPD)  
US Environmental Protection Agency  
Office of Pesticide Programs (7504P)  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

Subject: New Pesticide Application for Registration Technical and Manufacturing-Use  
"Refined Oil of *Nepeta cataria*"  
EPA File Symbol : 71654-

This letter and its attachments comprise DuPont's application for registration of a new insect repellent technical grade of active ingredient and manufacturing-use concentrate. There is a companion application for an end-use product, **Refined Oil of *Nepeta cataria* 15% Lotion**, which is submitted at the same time.

These two applications are based on the technology discussed with you and your staff on December 14, 2004, March 17, 2005 and February 27, 2006. During those discussions the active ingredient was referred to as **HYDROGENATED CATMINT OIL**. The product name and active ingredient name have been changed to facilitate global recognition and acceptance. Please also note the equivalency of 'catmint' with 'catnip' throughout.

Besides the **Refined Oil of *Nepeta cataria* 15% Lotion**, a substantially similar end-use formulation which contains **7% Refined Oil of *Nepeta cataria***, will be submitted within several weeks.

In support of the application, the following administrative documents are included:

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Five copies of labeling (2 pages each)  
Summary Data Requ. Biochemical Human Health Assessment  
Copy Check No. 3000068104 \$15,750.00 **PRIA B60**

Three copies of each study named in the transmittal document are also included.

Thank you for your assistance during the pre-registration phase of this program.

Should there be any questions, please feel free to call.

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas C. McEntee". The signature is fluid and cursive, with the first name "Thomas" being the most prominent part.

Thomas C. McEntee

Product Registration Manager

**[Thomas.C.McEntee@usa.dupont.com](mailto:Thomas.C.McEntee@usa.dupont.com)**



DuPont Chemical Solutions Enterprise

October 18, 2006

Dr. Russell Jones  
Biopesticides and Pollution Prevention Division (BPPD)  
US Environmental Protection Agency  
Office of Pesticide Programs (7504P)  
One Potomac Yard  
2777 South Crystal Drive  
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Thomas C. McEntee

Product Registration Manager

**Thomas.C.McEntee@usa.dupont.com**



DuPont Chemical Solutions Enterprise

October 18, 2006

Dr. Russell Jones  
Biopesticides and Pollution Prevention Division (BPPD)  
US Environmental Protection Agency  
Office of Pesticide Programs (7504P)  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

Subject: New Pesticide Application for Registration Technical and Manufacturing-Use  
"Refined Oil of *Nepeta cataria*"  
EPA File Symbol : 71654-

This letter and its attachments comprise DuPont's application for registration of a new insect repellent technical grade of active ingredient and manufacturing-use concentrate. There is a companion application for an end-use product, **Refined Oil of *Nepeta cataria* 15% Lotion**, which is submitted at the same time.

These two applications are based on the technology discussed with you and your staff on December 14, 2004, March 17, 2005 and February 27, 2006. During those discussions the active ingredient was referred to as **HYDROGENATED CATMINT OIL**. The product name and active ingredient name have been changed to facilitate global recognition and acceptance. Please also note the equivalency of 'catmint' with 'catnip' throughout.

Besides the **Refined Oil of *Nepeta cataria* 15% Lotion**, a substantially similar end-use formulation which contains **7% Refined Oil of *Nepeta cataria***, will be submitted within several weeks.

In support of the application, the following administrative documents are included:

Application for Pesticide Registration (EPA Form 8570-1)  
Transmittal Document  
CSF (EPA Form 8570-4) October 12, 2006  
Data Matrix EPA form (8570-35)  
Certification Data Citation (8570-34)  
Five copies of labeling (2 pages each)  
Summary Data Requ. Biochemical Human Health Assessment  
Copy Check No. 3000068104 \$15,750.00 **PRIA B60**

Three copies of each study named in the transmittal document are also included.

Thank you for your assistance during the pre-registration phase of this program.

Should there be any questions, please feel free to call.

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas C. McEntee". The signature is written in a cursive style with a large initial 'T' and a long horizontal stroke at the end.

Thomas C. McEntee

Product Registration Manager

**[Thomas.C.McEntee@usa.dupont.com](mailto:Thomas.C.McEntee@usa.dupont.com)**

DuPont Chemical Solutions Enterprise  
P. O. Box 80402  
Wilmington, DE 19880-0402



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Biopesticides and Pollution Prevention Division (BPPD)  
US Environmental Protection Agency  
Office of Pesticide Programs (7504P)  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

Subject: New Pesticide Application for Registration End-Use Insect Repellent  
**"Refined Oil of *Nepeta cataria* 15% Lotion"**  
EPA File Symbol : 71654-

This letter and its attachments comprise DuPont's application for registration of a new insect repellent end-use product, **Refined Oil of *Nepeta cataria* 15% Lotion**. There is a companion application for a new, technical grade of active ingredient and manufacturing-use concentrate, which is submitted at the same time.

These two applications are based on the technology discussed with you and your staff on December 14, 2004, March 17, 2005 and February 27, 2006. During those discussions the active ingredient was referred to as **HYDROGENATED CATMINT OIL**. The product name and active ingredient name have been changed to facilitate global recognition and acceptance. Please also note the equivalency of 'catmint' with 'catnip' throughout.

Besides the **Refined Oil of *Nepeta cataria* 15% Lotion**, a substantially similar end-use formulation which contains **7% Refined Oil of *Nepeta cataria***, will be submitted within several weeks.

In support of the application, the following administrative documents are included:

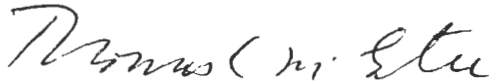
Application for Pesticide Registration (EPA Form 8570-1)  
Transmittal Document  
CSF (EPA Form 8570-4) October 12, 2006  
Data Matrix EPA form (8570-35)  
Certification Data Citation (8570-34)  
Five copies of labeling (4 pages each)  
Copy Check No. 3000068102 \$4200.00 PRIA B67

Three copies of each study named in the transmittal document are also included.

Thank you for your assistance during the pre-registration phase of this program.

Should there be any questions, please feel free to call.

Sincerely,



Thomas C. McEntee

Product Registration Manager

**Thomas.C.McEntee@usa.dupont.com**





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 10/12/2006

EPA Reg No./File Symbol 71654-

Page 2 of 3

Applicant's/Registrant's Name & Address

E.I. duPont de Nemours and Company, P.O. Box 80402 Wilmington, DE 19880-0402

Product

Refined Oil of Nepeta cataria

Ingredient Refined Oil of Nepeta cataria

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1100	Product Identity and Composition		E.I. duPont de Nemours and Company	Attached	
830.1200	Description of Starting Materials, Production and Formulation		E.I. duPont de Nemours and Company	Attached	
880.1400	Discussion of the Formation of Impurities		E.I. duPont de Nemours and Company	Attached	
830.1700	Preliminary Analysis		E.I. duPont de Nemours and Company	Attached	
830.1750	Certified Limits		E.I. duPont de Nemours and Company	Attached	
830.1800	Enforcement Analytical Method		E.I. duPont de Nemours and Company	Attached	
830.6302	Color		E.I. duPont de Nemours and Company	Attached	
830.6303	Physical State		E.I. duPont de Nemours and Company	Attached	
830.6304	Odor		E.I. duPont de Nemours and Company	Attached	
830.6313	Stability to Normal and Elevated Temperatures		E.I. duPont de Nemours and Company	Attached	
830.6315	Flammability		E.I. duPont de Nemours and Company	Attached	
830.6317	Storage Stability		E.I. duPont de Nemours and Company	Attached	
830.6319	Miscibility		E.I. duPont de Nemours and Company	Attached	
830.6320	Corrosion Characteristics		E.I. duPont de Nemours and Company	Attached	

Signature

Name and Title

Thomas C. McEntee Product Registration Manager

Date

10/12/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
1200 Pennsylvania Avenue, N.W.  
WASHINGTON, D.C. 20460

Form Approved OMB Nos. 2070-0060; 2070-0057;  
2070-0107; 2070-0122; 2070-0164

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DATA MATRIX

Date	October 12, 2006	EPA Reg No./File Symbol	71654-	Page	1 of 3
Applicant's/Registrant's Name & Address		Product			
E. I. du Pont de Nemours and Company; ESL 402/3224A P.O. Box 80402 Wilmington, DE 19880-0402		Refined Oil of Nepeta cataria - technical and manufacturing-use concentrate			

Ingredient Refined oil of Nepeta cataria					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute Oral Toxicity		E.I du Pont de Nemours		Attached
870.1200	Acute Dermal Toxicity		E.I du Pont de Nemours		Attached
870.1300	Acute Inhalation Toxicity		E.I du Pont de Nemours		Attached
870.2400	Primary Eye Irritation		E.I du Pont de Nemours		Attached
870.2500	Primary Dermal Irritation		E.I du Pont de Nemours		Attached
870.2600	Skin Sensitization-Local Lymph Node Assay		E.I. du Pont de Nemours		Attached
870.3100	90-day Oral Toxicology - Rat		E.I. du Pont de Nemours		Attached
870.7800	Immunotoxicology 28 day		E.I. du Pont de Nemours		Attached
870.3700	Prenatal Developmental Toxicity		E.I. du Pont de Nemours		Attached
OECD No. 428	Dermal Absorption In Vitro method		E.I. du Pont de Nemours		Attached
870.3200	28-day Repeated Dose Dermal Toxicity - Rats		E.I. du Pont de Nemours		Attached
870.6200	Acute Oral Neurotoxicity		E.I. du Pont de Nemours		Attached
870.5100	Bacterial Reverse Mutation		E.I. du Pont de Nemours		Attached
870.5395	Mammalian Erythrocyte Micronucleus Test		E.I. du Pont de Nemours		Attached
870.5300	In Vitro Mammalian Cell Gene Mutation Test		E.I. du Pont de Nemours		Attached
Signature <i>Thomas C. McEntee</i> Oct 12, 2006			Name and Title		Date
			Thomas C. McEntee, Product Registration Manager		Oct. 12, 2006

# MEMORANDUM

DATE: 11 / 17 / 06

71654-EN  
(Technical)

TO: BPPD (91), Regulatory Manager

FROM: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted in OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☐ fully accepted submission  
☒ partially accepted submission  
☐ rejected submission

